

The Efficacy Of A Topical Naturopathic Complex (Allium sativum Ø,
Hydrastis canadensis Ø, Apis mellifica D3 and Urtica urens D3) In
The Treatment Of Tinea pedis.

By

Prashadhna Devi Maharaj

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

I Prashadhna Devi Maharaj do declare that this mini-dissertation is
representative of my own work, both in conception and execution.

Signature of student

Date of signature

APPROVED FOR FINAL SUBMISSION

Signature of supervisor

Dr. C.M. Hall

B. Sc (PU for CHE); M. Tech. Hom (T.N)

Date of signature

To mum and dad

Your hard work and endless
sacrifices have made it all
possible

To Shri Gurudev

In whose Divine name I take refuge

Matha, Pitha, Gurudevam

ACKNOWLEDGEMENTS

I would like to extend by sincerest gratitude to:

Dr. Corné Hall – For all her assistance and guidance as supervisor throughout this study. Your warmth and kindness will always be remembered.

Dr. D.F. Naude – For his assistance with the statistical analysis of the data.

Dr. M. Maharaj - My homoeopath. For helping me through times when sanity and reason seemed to fail.

Dr. C.R. Hopkins & Dr. I.M.S. Couchman for their assistance as clinicians

Most importantly, I would like to thank all those participants who completed this study.

ABSTRACT

Tinea pedis, more commonly known as “Athlete’s foot”, is a common acute infection that occurs in warm, humid climates (Fitzpatrick, *et al.* 1992:98). Warmth, humidity, trauma and occlusion such as non-breathable footwear increase the susceptibility to infection (Prescott, *et al.* 1999:814). The infection can become chronic in people who are more susceptible such as patients who are immuno-suppressed or those who have Diabetes mellitus (al Hassan, *et al.* 2004: 1).

The aim of this placebo-controlled double-blind study was to evaluate the effectiveness of a topical naturopathic complex comprising of *Allium sativum* mother tincture (Ø), *Hydrastis canadensis* (Ø), *Apis mellifica* (D3) and *Urtica urens* (D3) (in an aqueous cream base) in the treatment of *Tinea pedis*. The complex utilized in this study is regarded as naturopathic because the remedies comprising the complex were selected for the following reasons:

- *Allium sativum* and *Hydrastis canadensis*, each utilized in mother tincture, were selected for their antifungal properties.
- *Apis mellifica* and *Urtica urens*, each utilized in D3 potency were selected because their skin symptomatology most accurately matched the symptoms associated with “Athlete’s foot”.

This study focused on individuals between the ages of 18 and 60 years residing in the greater Durban area. It was designed for 30 participants, consisting of two equal random groups, with one group receiving the complex and the second

group receiving the placebo. Extra participants were, however, recruited to allow for dropouts. Data for statistical analysis was obtained from all participants who completed the trial. The final number of participants that completed the trial was 31. The treatment group comprised of 15 participants and the placebo group comprised of 16 participants. The participants had a follow up consultation 2 weeks after the 1st consultation and a final consultation 2 weeks after the follow-up consultation.

Data for this study was obtained from the Patient Perception Questionnaire (PPQ) (Appendix D) and Visual Scale for the Assessment of the Appearance of the Feet (VS) (Appendix E). The Visual scale provided an objective measurement and the PPQ provided a subjective measurement.

For each type of scale, the Wilcoxin's Signed Rank test was conducted to test for a significant difference in population means within each group i.e. before and after treatment. The difference between the pre-treatment and post-treatment within each group was calculated. Frequency tables were also utilized for selected questions in the PPQ within each group. All the results were positive i.e. there were significant differences within each of the two groups on both scales where $p < 0.05$. When results were compared between the two groups, utilizing the Kruskal Wallis Test, no significant differences were noted ($p > 0.05$).

The treatment administered in this study namely, the topical naturopathic complex, was successful in reducing the signs and symptoms of *Tinea pedis*,

but, because there was no significant difference in the effect between the topical naturopathic complex and the placebo (an aqueous cream base impregnated at a 10% volume-to-volume concentration with plain ethanol), it is concluded that the topical naturopathic complex comprising of *Allium sativum* mother tincture (Ø), *Hydrastis canadensis* (Ø), *Apis mellifica* (D3) and *Urtica urens* (D3) (in an aqueous cream base) was *per se* not effective in the treatment of *Tinea pedis*.

TABLE OF CONTENTS	PAGE
Dedication	
Acknowledgements	I
Abstract	II
Table of Contents	V
List of Tables	XI
List of Figures	XIV
Definition of Terms	XV
CHAPTER ONE: INTRODUCTION	1
1.1 Problem statement	2
1.2 Objectives	2
1.2.1 Objective one	2
1.2.2 Objective two	3
CHAPTER TWO: REVIEW OF RELATED LITERATURE	4
2.1 Introduction	4
2.2 The Structure of the Skin	4
2.2.1 The Epidermis	4
2.3 Fungi	7

2.3.1 Classification	7
2.4 Tinea pedis	7
2.4.1 Definition	7
2.4.2 Epidemiology	8
2.4.3 Aetiology	8
2.4.4 Clinical Presentations	9
2.5 Diagnosis	14
2.5.1 Signs	14
2.5.2 Symptoms	14
2.5.3 Laboratory Tests	14
2.6 Current Allopathic Treatment	15
2.7 Complementary and Alternative Therapies	17
2.8 Naturopathy	18
2.9 Homoeopathy	19
2.9.1 The Law of Similars	19
2.9.2 Topical Homoeopathic Treatment	19
2.9.3 Polypharmacy	20
2.9.4 Placebo	25

3.4.7.2 Procedure 2: Kruskal Wallis Test	37
---	-----------

CHAPTER FOUR: RESULTS

4.1 Introduction	39
4.2 Criteria Governing the Admissibility of Data	39
4.2.1 Demographic Data	40
4.2.2 Bargraphs Representing the Comparison between the Means of the Visual Scale (VS) for the treatment and Placebo Groups	41
4.3 Statistical Analysis	46
4.3.1 Procedure 1 (Intra-Group Comparison): Wilcoxon's Signed Rank Test	46
4.3.1.1 Patient Perception Questionnaire (PPQ) (Appendix D) - Wilcoxon's Signed Rank Test	46
4.3.1.2 Frequency Tables for the Patient Perception Questionnaire (PPQ)	48
4.3.1.3 Visual Scale for the Assessment of the Appearance of the Feet (VS) (Appendix E) - Wilcoxon's Signed Rank Test	71

4.3.2 Procedure 2 (Inter-Group Comparison):	72
Kruskal Wallis Test	
4.3.2.1 Patient Perception questionnaire (PPQ)	72
(Appendix D) - Kruskal Wallis Test	
4.3.2.2 Visual Scale for the Assessment of Appearance of	74
Feet (VS) (Appendix E) - Kruskal Wallis Test	
CHAPTER FIVE: DISCUSSION	
Discussion	75
5.1 Demographics	76
5.2 Problems Encountered During This Trial	77
CHAPTER SIX:	79
CONCLUSION AND RECOMMENDATIONS	79
REFERENCES	81
INTERNET REFERENCES	87

LIST OF TABLES	PAGE
Table 4.1 Comparison within each group (treatment and placebo) between consults 2 & 1, consults 3 & 2, and consults 3 & 1 respectively (Wilcoxon's Signed Rank Test)	46
Table 4.2 (A) Frequency table (Treatment group): Q2 'Has your "Athlete's foot" changed at all since treatment?'	48
Table 4.2 (B) Frequency table (Placebo group): Q2 'Has your "Athlete's foot" changed at all since treatment?'	49
Table 4.3 (A) Frequency table (Treatment group): Q2.1 'If your "Athlete's foot" has changed, how has it changed?'	51
Table 4.3 (B) Frequency table (Placebo group): Q2.1 'If your "Athlete's foot" has changed, ' how has it changed?'	53
Table 4.4 (A) Frequency table (Treatment group): Q3 ' Has the appearance of your feet changed/'	55
Table 4.4 (B) Frequency table (Placebo group): Q3 'Has the appearance of your feet changed?'	57

Table 4.5 (A) Frequency table (Treatment group):	59
Q6 'Has the surface texture of your skin change?'	
Table 4.5 (B) Frequency table (Placebo group):	61
Q6 'Has the surface texture of your skin changed?'	
Table 4.6 (A) Frequency table (Treatment group):	63
Q7 'Has the peeling of your skin improved?'	
Table 4.6 (B) Frequency table (Placebo group):	65
Q7 'Has the peeling of your skin improved?'	
Table 4.7 (A) Frequency table (Treatment group):	67
Q9 'How do you perceive the treatment to be thus far?'	
Table 4.7 (B) Frequency table (Placebo group):	69
Q9 'How do you perceive the treatment to be thus far?'	
Table 4.8 Comparison within each group (treatment and placebo)	71
between first and final consultation for the Visual scale (VS) -	
Wilcoxon's Signed Rank Test	
Table 4.9 Inter-group comparisons for all 3 consultations for the	72
Patient Preception Questionairre (PPQ) - Kruskal Wallis Test	

Table 4.10 Inter-group comparison between the first and

74

final consultations for the Visual scale (VS) -

Kruskal Wallis Test

LIST OF FIGURES	PAGE
Figure A - The Skin	5
Figure B - The Epidermis	6
Figure C - Interdigital Tinea pedis	11
Figure D - Moccasin - type Tinea pedis	12
Figure E - Bullous Tinea pedis	13
Figure 4.1 Pie - Chart -	40
showing the percentage of male and female participants	
Figure 4.2 Barchart showing Visual Scale scores for	41
'Red blotches' before and after treatment	
Figure 4.3 Barchart showing Visual Scale scores for	42
'Cracked skin' before and after treatment	
Figure 4.4 Barchart showing Visual Scale scores for	43
'Dry skin' before and after treatment	
Figure 4.5 Barchart showing Visual Scale scores for	44
'Peeling skin' before and after treatment	
Figure 4.6 Barchart showing Visual Scale scores for	45
'Bleeding skin' before and after treatment	

DEFINITION OF TERMS

AIDS

Acquired immunodeficiency syndrome (AIDS) is a disorder of cell-mediated immunity characterized by opportunistic infections, malignancies, neurological dysfunction, and a variety of other syndromes (Beers, *et al.* 1999:1312).

ALKALOID

Yasgur (1992:19) defines an alkaloid as any of various physiologically active nitrogen-containing organic bases derived from plants, i.e. nicotine, quinine, cocaine, atropine etc. They are generally bitter in taste and alkaline in reaction and unite with acids to form salts. Their common names usually end in –ine.

ALLOPATHY

Allopathy is the treatment of disease using medicines whose effects are different from those of the disease being treated and which have no relationship to the disease symptoms. Allopathy is based on the principle of *contraria contraries*, or the Law of Opposites (Yasgur, 1997:9).

ANTIFUNGAL

Van Wyk & Wink (2004:434) defines an antifungal as a substance that either kills or inhibits the growth of fungi.

ANTIOXIDANT

A substance that protects cells from the damaging effects of highly reactive

oxygen molecules called free radicals. The body makes some antioxidants. Others such as vitamins C and E are obtained through diet and supplements (Anders, *et al.* 1999:399).

AZOLES

These are antifungal drugs that act by interfering with the synthesis of ergosterol. They block the cytochrome P450-dependent 14- α -demethylation lanosterol, which is a precursor of ergosterol in fungi and cholesterol in mammalian cells. The fungal cytochrome P450s are approximately 100-1000 times more sensitive to the azoles than mammalian systems. Azoles are fungistatic drugs (Brooks, *et al.* 2001:557).

CANDIDA ALBICANS

Candida albicans is a fungus that is a normal member of the micro flora of the gastrointestinal tract, respiratory tract, vaginal area and mouth. In healthy individuals, *C. albicans* does not produce disease as other microbes of the body suppress its growth. When the body's balance is disturbed, *Candida* may multiply rapidly and produce infection called candidiasis (Prescott, *et al.* 1999:818).

CLASSICAL HOMOEOPATHY

Swayne (2000:42) defines homoeopathy as:

1. Doctrine or school of homoeopathic philosophy and therapeutics claiming to be based on strict Hahnemannian principles.
2. Therapeutic method using a single medicine in a single prescription.

DIABETES MELLITUS

Diabetes mellitus is defined as a syndrome, which is characterized by hyperglycemia (raised blood sugar levels) resulting from absolute or relative impairment in insulin secretion and / or insulin action (Beers *et al.* 1999:165).

GYNAECOMASTIA

Berkow (1997:1107) defines gynaecomastia as breast enlargement in males. Breast enlargement may occur during puberty. This enlargement is normal and transient, lasting only a few months to a few years. It may also be caused by certain diseases, certain drug therapies or less commonly by hormonal imbalance.

HEPATOTOXIC

A drug or chemical substance that causes damage to the liver, either reversible or irreversible, is referred to as “hepatotoxic”. These substances usually cause “hepatitis” (inflammation of the liver), affecting the normal functioning of this organ (Tierney, *et al.* 2000:669-670).

HERBAL MEDICINE

Herbal medicine is defined as the medicinal use of plants, parts of plants or plant extracts. Words synonymously used are: herbalism, phytotherapy (Swayne, 2000:98).

IMMUNO-SUPPRESSION

It the suppression of the normal functioning of the immune system to fight off infection and illness. It usually occurs in Immunodeficiency Disorders which are a group of diverse conditions in which the immune system does not function adequately, so that infections are more common, recur more frequently, are unusually severe, and last longer than usual (Berkow, 1997:816).

IN VITRO

In vitro, which is Latin, means “in glass”. These studies involve the use of cell-free extracts to search for enzymes and metabolic intermediates that might belong to a particular metabolic pathway (Prescott, *et al.* 1999:193). The process therefore takes place outside a living body and in an artificial environment (Murray, 1995:399).

MOTHER TINCTURE

Liquid preparations resulting from the extraction of suitable source material in water-ethanol mixtures, which form the starting point for the production of most homoeopathic medicines. Comminution (breaking down into fragments), followed by standard maceration and squeezing techniques are used on fresh plants and succulents, while dried specimens are subjected mainly to percolation with alcohol on a column (Swayne, 2000:140).

PLACEBO

Swayne (2000:162) defines placebo as:

1. A substance with no active biological properties, knowingly or unknowingly used to exert a beneficial therapeutic effect, or given to satisfy a patient's expectations of treatment.
2. An inactive agent used for comparison with the substance or method to be tested in a controlled trial, and indistinguishable from it.

POLYPHARMACY

Watson (1991: 71) defines polypharmacy as a method that encompasses any prescribing technique in which two or more remedies are prescribed simultaneously, either in alternation with each other or as a combined formula.

POTENCY

Swayne (2000: 166) defines potency as:

1. Power; ability to cause effects.
2. The medicinal power of a homoeopathic medicine released or developed by dynamisation or potentiation.

POTENTISATION

A multi-step process developed by Hahnemann by which the medicinal power of a homoeopathic medicine is released or increased, involving serial dilution with succussion, or using trituration or fluxion (Swayne, 2000:169).

SIMILLIMUM

Gaier (1991:509) defines simillimum as the single homoeopathic medicine the drug picture of which most nearly approaches the total symptom complex of the patient, which will certainly cure the patient, if the patient's condition is within reversible limits.

URTICARIA

Yasgur (1997:271) defines urticaria as a generic term for oedematous (fluid-filled) hives or rashes. From the nettle, *Urtica dioica*, a weed which causes a stinging sensation and produces a rash which usually fills with fluid.

VOLATILE OILS

Also known as essential oils, are usually complex mixtures of a wide variety of organic compounds (e.g. Alcohols, acids, etc.) that evaporate when exposed to air. They generally represent the odoriferous principles of plants (Murray, 1995:397).

CHAPTER 1

INTRODUCTION

Fungi that thrive only in the uppermost tissue of the skin cause superficial fungal infections of the skin. "Tinea" is the term used generically for these fungal infections, which are usually referred to as "Ringworm" (Fitzpatrick, *et al.* 1992:98). "Pedis" is a Latin word and means "foot" (Tulloch, S. (ed.) 1994:1120). Tinea pedis is therefore a superficial fungal infection of the feet and is more commonly known as "Athlete's Foot" (Tierney, *et al.* 2000:141).

Tinea pedis is a very common acute infection that occurs in warm humid climates (Fitzpatrick, *et al.* 1992:98). Warmth, humidity, trauma and occlusion increase susceptibility to infection (Prescott, *et al.* 1999: 814) It can become chronic in patients who are more susceptible such as patients who are immuno-suppressed or have diabetes mellitus (Al Hassan, *et al.* 2004: 1).

The current trends in the allopathic treatment of "Athlete's Foot" include the use of topically and systemically applied antifungal drugs. Topical treatment is with drugs such as Clotrimazole and Miconazole, while oral treatment includes drugs such as Griseofulvin and Terbinafine (brand name Lamisil®) (Prescott, *et al.* 1999). Generally, simple Tinea pedis responds well to the local application of cream and powder formulations of Clotrimazole (Brooks, Butel and Morse, 2001:559). The use of allopathic medicines is however, not without complication due to short-term effectiveness, side effects and cost implications (Tierney, *et al.*

2000:142).

There have been various *in vitro* studies, which have demonstrated the effectiveness of both *Allium sativum* and *Hydrastis canadensis* as antifungal agents. Arora (1999) demonstrated the inhibitory effects of *Allium sativum* on a broad spectrum of yeasts and bacteria; De Smidt (2001) demonstrated the inhibitory effects of *Allium sativum* on *Candida albicans*, while Budree (2003) demonstrated the inhibitory effects of *Hydrastis canadensis* on *Candida albicans*. There is however, a lack of material with regards to clinical trials in Homoeopathy.

1.1 Problem statement

This study proposed to evaluate the effectiveness of a topical naturopathic complex comprising of *Allium sativum* mother tincture (Ø), *Hydrastis canadensis* mother tincture (Ø), *Apis mellifica* D3 and *Urtica urens* D3 (in an aqueous cream base) in the treatment of *Tinea pedis* (“Athlete’s Foot”). It focused on individuals between the ages of 18 and 60 residing in the greater Durban area.

1.2 Objectives

1.2.1 OBJECTIVE ONE: The first objective of this randomized double blind placebo-controlled (Aqueous cream) study proposed to evaluate the efficacy of a topical naturopathic complex (*Allium sativum* Ø, *Hydrastis canadensis* Ø, *Apis mellifica* D3 and *Urtica urens* D3) in the treatment of *Tinea pedis* (“Athlete’s Foot”) in terms of the patient’s perception determined by the Patient Perception Questionnaire.

1.2.2 OBJECTIVE TWO: the second objective of this randomized double blind placebo-controlled (Aqueous cream) study proposed to evaluate the efficacy of a topical naturopathic complex (Allium sativum Ø, Hydrastis canadensis Ø, Apis mellifica D3 and Urtica urens D3) in the treatment of Tinea pedis (“Athlete’s Foot) in terms of visible improvement determined by visual scoring.

This study therefore proposed to investigate the efficacy of a topical naturopathic complex (Allium sativum Ø, Hydrastis canadensis Ø, Apis mellifica D3 and Urtica urens D3 in the treatment of Tinea pedis (“Athlete’s Foot’). The researcher hoped that the study would demonstrate the efficacy of a topical naturopathic complex as an effective and safe alternative to existing treatments.

CHAPTER TWO

REVIEW OF THE RELATED LITERATURE

2.1 INTRODUCTION

The following discussion will focus on the literature related to Tinea pedis. It seeks to explore the current understanding of this condition in terms of the epidemiology, aetiology, signs and symptoms and management.

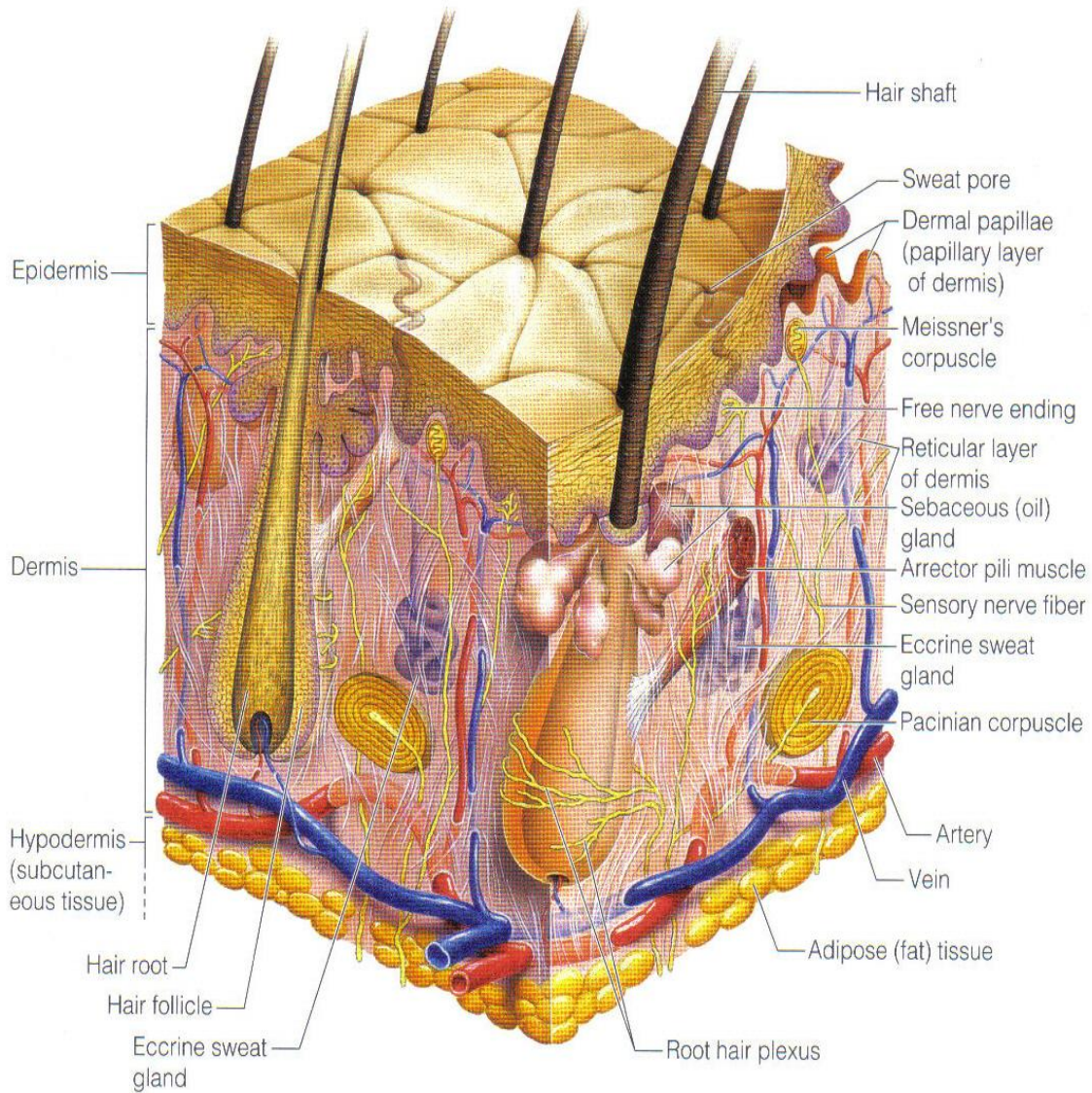
2.2 THE STRUCTURE OF THE SKIN (see figure A, pg 5)

The skin consists of two parts, the epidermis which is made up of stratified squamous epithelium, and the dermis, which consists of dense connective tissue (Mackie. 1991). For the purpose of this discussion, we will be focusing briefly on the epidermis, as this is the layer of the skin that is the site of the fungal infection.

2.2.1 THE EPIDERMIS (see figure B, pg 6)

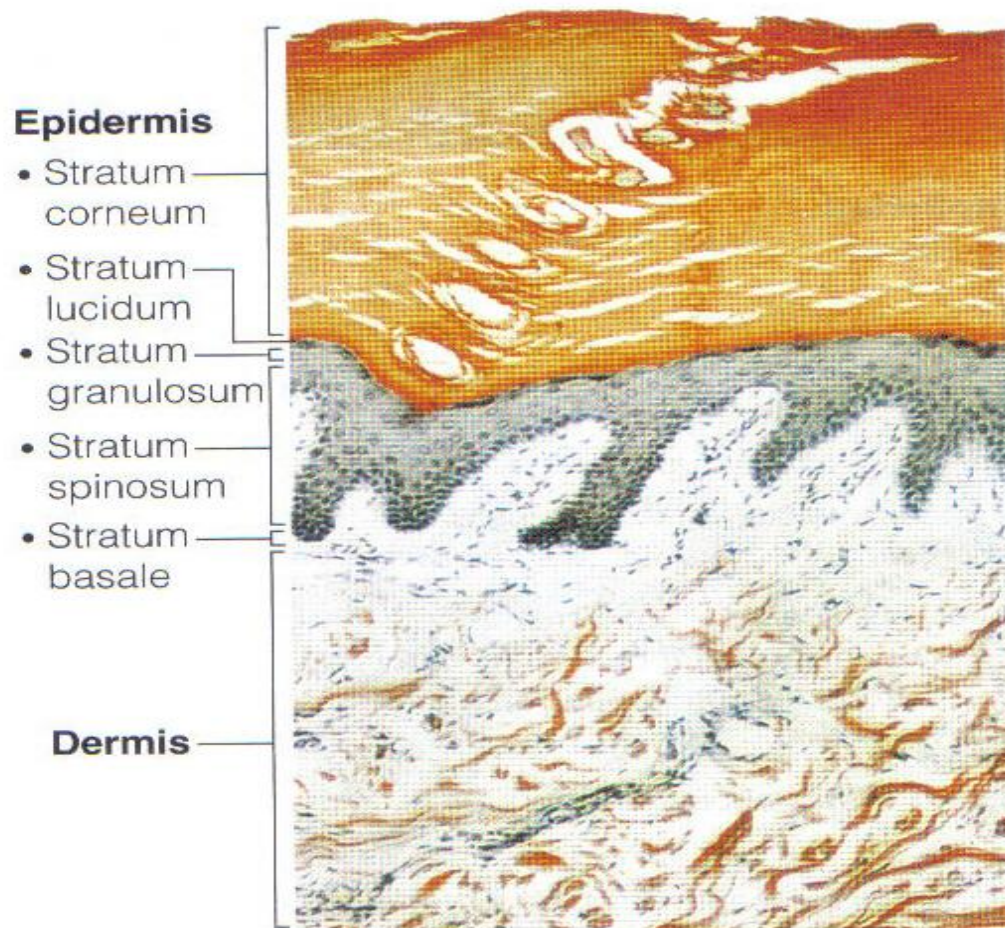
The epidermis is composed of five layers called strata. They are, from innermost to outermost, stratum basale, stratum spinosum, stratum granulosum, stratum lucidum and stratum corneum. Stratum basale is the proliferative layer where cells constantly undergo division, stratum spinosum and granulosum, the layers towards which the cells move and become flatter and more keratinised, eventually forming the clear layer stratum lucidum. Stratum corneum is the outermost layer, consisting of dead cell remnants, completely filled with keratin, which are referred to as cornified or horny cells (Marieb. 2000:95 -97).

FIGURE A: The skin



(Marieb, 2003)

FIGURE B: The epidermis



(Marieb, 2003)

2.3 FUNGI

2.3.1 CLASSIFICATION

Cutaneous mycoses or superficial fungal infections are caused by Dermatophytes (Brooks, Butel and Morse, 2001: 535).

Dermatophytes are fungi that thrive only in the superficial keratinised tissue of the skin such as the stratum corneum (figure B, pg 5), hair and nails.

The three genera are *Microsporum*, *Trichophyton* and *Epidermophyton*, which cause dermatophytosis, or “tinea”, a term used generically for dermatophytosis (Fitzpatrick, *et al.* 1992: 98).

2.4 TINEA PEDIS

2.4.1 DEFINITION

Fungal infections of the skin can occur in different regions of the body and have been named according to the site of the infection. *Tinea capitis* affects the scalp, *Tinea barbae* affects the face, *Tinea unguum* affects the nails, *Tinea manuum* affects the hands and *Tinea cruris* affects the groin (Al Hasan, *et al.* 2004). *Tinea pedis*, otherwise known as “*Athletes foot*”, is a common fungal infection affecting the feet and is the focus of this study.

The principal manifestations of this condition are peeling and cracking of the skin, accompanied by pain and pruritus (itching). The condition is generally harmless but unusually irritating, producing significant discomfort to the sufferer (Anders, *et al.* 1999).

2.4.2 EPIDEMIOLOGY

Athlete's foot is found more commonly in adolescents and young adults, especially in people who use communal changing facilities, showers and swimming pools (Mackie, 1991: 145).

2.4.3 AETIOLOGY

- Trauma and contact (Brooks, Butel and Morse, 2001: 536).
- Host susceptibility is increased by moisture, warmth, specific skin chemistry, composition of sebum and perspiration, youth and genetic predisposition (Brooks, Butel and Morse, 2001:536).
- Incidence is higher in hot, humid climates and under crowded living conditions (Brooks, Butel and Morse, 2001:536).
- Non-breathable footwear provides warmth and moisture, creating a favourable condition for the growth of fungi (Brooks, Butel and Morse, 2001:536).
- An increase in immune deficiency diseases (AIDS) and an increase in the number of patients receiving chemotherapy, steroids, organ transplants, and parenteral nutrition, have resulted in an increased incidence of Tinea pedis (Al Hasan, *et al.* 2004).
- Patients who are obese, elderly, or have systemic problems such as diabetes mellitus are at increased risk (Al Hasan, *et al.* 2004).

2.4.4 CLINICAL PRESENTATIONS (see pgs 11-13)

Tinea pedis may manifest as one of three typical variants which are, the moccasin type, interdigital and vesiculobullous type distribution.

(Fitzpatrick, *et al.* 1992:101)

- INTERDIGITAL-TYPE TINEA PEDIS (figure C, pg 11)

This is the most common form and usually affects the fourth and fifth interdigital spaces. The infection may spread to the underside of the toes. Interdigital tinea pedis may present as one of two types.

The first type is called dermatophytosis simplex. The skin of the interdigital space is dry and scaly with low-grade peeling. This type is usually asymptomatic with only occasional pruritis.

The second type is called dermatophytosis complex. This type presents as wet, macerated interdigital spaces. Fungal infection accompanied by wet conditions increases the chance of bacterial invasion, especially where the skin has been broken (Al Hasan, *et al.* 2004).

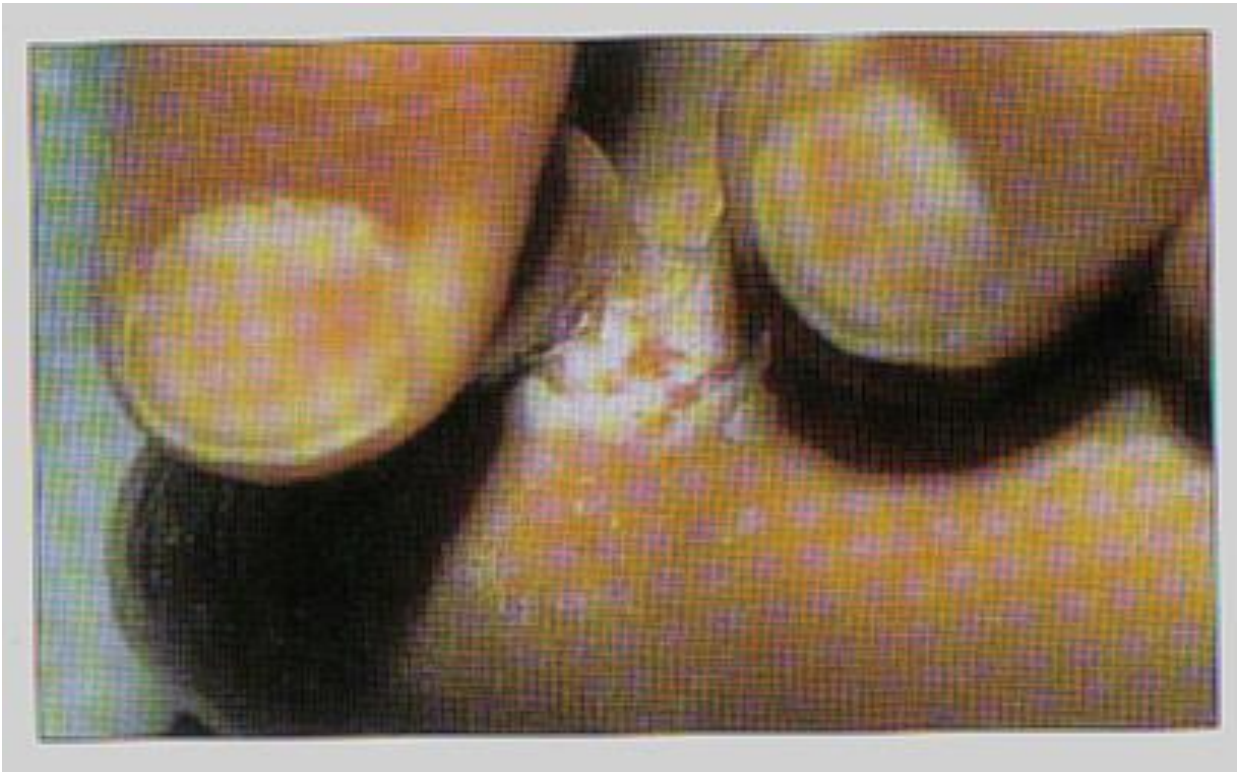
- MOCCASIN-TYPE TINEA PEDIS (figure D, pg 12)

This is a more prolonged and severe type of tinea pedis. It covers the bottom and lateral aspects of the foot and has the appearance of a slipper or moccasin covering the foot. The skin becomes dry, hyperkeratotic and scaling, with cracking and peeling. This eventually leads to pruritis, pain and bleeding (Fitzpatrick, *et al.* 1992:101).

- VESICULOBULLOUS-TYPE TINEA PEDIS (figure E, pg 13)

This type, which is less common, comprises of fluid-filled vesicles occurring on the instep and plantar surfaces of the feet. The fluid-filled vesicles are usually clear, but if pus is present then bacterial infection must be considered and ruled out by microscopy or culture (Al Hasan, *et al.* 2004).

FIGURE C: Interdigital tinea pedis



(White, 1997)

FIGURE D: Moccasin-type tinea pedis



(White, 1997)

FIGURE E: Bullous tinea pedis



(White, 1997)

2.5 DIAGNOSIS

The diagnosis of Tinea pedis is based on the history and clinical appearance of the feet. Al Hasan (2004) states that cultures and histological examinations are rarely required. Direct microscopy of potassium hydroxide (KOH) may accompany diagnosis through history and clinical appearance.

2.5.1 SIGNS

- Scaling, maceration, vesicles or bullae formation;
- Skin appears red with opaque white scales;
- Usually located in the third and fourth interdigital spaces, later extending to the sole, especially the arch;
- Scaling and hyperkeratosis (thickening of the skin) as the condition becomes chronic (Fitzpatrick, *et al.* 1992:101).

2.5.2 SYMPTOMS

- Simple dermatophyte infection is relatively asymptomatic and uncomplicated except for only mild pruritus (itching) and burning sensations (White, 1997:154 - 155).
- When the infection becomes chronic, with peeling and cracking, then pain and pruritus occur (Brooks, Butel and Morse, 2001: 537).

2.5.3 LABORATORY TESTS

- MICROSCOPY

Specimens (scrapings of skin and nails) are placed in a drop of 10 to 20%

potassium hydroxide (KOH) solution and viewed on a slide under fluorescent microscope (Brooks, Butel and Morse, 2001: 538).

- CULTURE

Skin scrapings are inoculated onto inhibitory mold agar or Sabouraud's agar plates. The plates are incubated at room temperature for one to three weeks, and are further examined through microscopy if required (Brooks, Butel and Morse, 2001: 538).

2.6 CURRENT ALLOPATHIC TREATMENT

The allopathic treatment of "*Athletes foot*" involves the use of both topically and systemically applied drugs.

Topical antifungal azoles such as Clotrimazole are available in several formulations, and simple Tinea pedis responds well to the local application of creams or powders (Brooks, Butel and Morse, 2001:559). This type of treatment, however, is regarded in naturopathy, particularly in homoeopathy, as suppression (Digby, 1997:3). By suppression it is meant that conventional medicine seeks only to treat the symptoms of the disease, with disregard for the individual. The aim of Naturopathy is to restore the balance of the body with the use of herbal medicine, vitamins and minerals or homoeopathy. In homoeopathy, the patient is treated with substances which act in the same way as the reactive mode of the individual, in the same way as his defense mechanisms, and thus in cooperation with the individual (Jouanny, *et al.* 1996:12).

Systemic antifungal therapy is employed in patients who fail to respond to topical treatment (Bell-Syer, *et al.* 2002).

The systemic drugs are known to have certain side effects (Appendix H).

Griseofulvin is an antibiotic formed by *Penicillium*. It is given orally to treat chronic dermatophyte infections. It is thought to inhibit cell division and inhibit protein and nucleic acid synthesis. The side effects of Griseofulvin include headaches, gastrointestinal upset and allergic reactions (Prescott, Harley and Klein, 1999: 692).

Ketoconazole is a well tolerated anti fungal agent, but if used over prolonged periods, becomes hepatotoxic. Ketoconazole may also cause a variety of reversible side effects such as gynaecomastia, decreased libido, impotence, menstrual irregularity, and occasionally adrenal insufficiency (Brooks, Butel and Morse, 2001:559).

Terbanafine (Lamasil) is a more effective oral treatment than Griseofulvin (Bell-Syer, *et al.* 2002), but the common side effects of Terbanifine are gastro – intestinal symptoms (fullness, loss of appetite, nausea, mild abdominal pain, diarrhea), or skin reactions (rash, urticaria) (Medical Chronicle, 1995).

In cases where the infection is cleared by systemic therapy, the patient is encouraged to begin maintenance with topical therapy, as recurrences are common (Tierney, *et al.* 2000:142).

Allopathic antifungal drug therapy is not without side effects, it does not prevent

recurrences, and it is expensive (Tierney, *et al.* 2000:142).

2.7 COMPLEMENTARY AND ALTERNATIVE THERAPIES

In milder cases of “*Athletes foot*”, supplements can be used as an inexpensive alternative to treating this infection (Anders, *et al.* 1999: 62).

Some of the alternative supplements are:

- **Vitamin C**, which is an antioxidant, and promotes immune function, aiding the body in fighting fungal infections (Anders, *et al.* 1999: 62 – 63).
- **Tea tree oil**, a natural antifungal agent. Topical preparations include creams and lotions containing tea tree oil (Anders, *et al.* 1999: 63).
- **Calendula officinalis, which** is available in creams or lotions, is widely available in health shops. It relieves inflammation, soothes the skin and promotes healing (Anders, *et al.* 1999: 63).

Basic feet care steps that can be followed to prevent or hasten improvement of

“*Athletes foot*”:

The essential factor in the prevention of *Tinea pedis* is personal hygiene (Tierney, *et al.* 2000:142).

- Use rubber or wooden sandals in community showers and bathing areas (Tierney, *et al.* 2000:142).
- Keep the feet clean and dry. Wash the towel after each use (Anders, *et al.* 1999: 63).
- Careful drying between the toes is important. A hairdryer used on a low setting may be used before dressing (Tierney, *et al.* 2000: 142).

- Wear clean, dry socks. Air shoes after each use (Anders, *et al.* 1999:63).
- Go barefoot when possible or opt for sandals or well-ventilated shoes that allow the feet to breathe (Anders, *et al.* 1999:63).

2.8 NATUROPATHY

Naturopathy is defined by Yasgur (1992:95) as “system of therapeutic medical science comprising many natural healing techniques.” It is a ‘drugless’ system that focuses on the use of herbal medicine, spinal and soft tissue adjustments or manipulations such as chiropractics, homeopathy, botanical medicines, hydrotherapy, acupuncture, nutritional guidance, and supplements (vitamins, glandular extracts, enzymes, etc.).”

Naturopathy focuses on the concept of Homoeostasis in relation to health and disease. Homoeostasis has been defined as the self-regulating or balancing mechanism of the body. The aim of the natural therapist is to enhance or restore the balance of the body with the use of herbology, vitamins and mineral or homoeopathy. The restoration of balance occurs on all the levels of the being, namely mental, emotional and physical (Jacka, 1995:3).

For the purpose of this study, a brief discussion on the therapy of homoeopathy will follow.

2.9 HOMOEOPATHY

2.9.1 THE LAW OF SIMILARS

Homoeopathy is a system of treatment based on the principle “Like Cures Like,” meaning that the substance which produces certain symptoms when administered to healthy people can, when administered in minute doses, cure the same symptoms in the sick (De Schepper, 2001: 26). A German physician, Christian Samuel Hahnemann, developed this method of treatment in about 1790 (Jouanny, *et al.* 1996:9).

The three fundamental principles of homoeopathy are:

- “*similia similibus* – like with likes”. “That is, in order to cure disease, we must seek medicines that can excite similar symptoms in the healthy human body.” (Kayne, 1997:25).
- To select the homoeopathic remedy that corresponds not only to the pathognomonic signs of the disease manifestation, but also to the symptoms, which are specific to or characteristic of the individual (Jouanny, *et al.* 1996:21).
- The use of homoeopathic medicines in extremely diluted (infinitesimal) doses prepared by succussion or trituration (Jouanny, *et al.* 1996:61).

2.9.2 TOPICAL HOMOEOPATHIC TREATMENT

Kayne (1997:127), states that most topical preparations, although frequently described as ‘homoeopathic’, are in essence herbal in nature, usually having been prepared by combining a mother tincture with a suitable vehicle such as

soft paraffin, light liquid paraffin, aqueous cream or alcohol.

The complex utilized in this study contained the ingredients *Allium sativum* Ø and *Hydrastis canadensis* Ø. These remedies were utilized in tincture form to investigate their antifungal activity as herbal tinctures. A discussion of these antifungal properties will follow in the discussion of the individual remedies (pg 22 -23).

Kayne (1997:127) also states that remedies in low potencies, typically 6x, are also used as active ingredients in most topical preparations.

The use of external homoeopathic remedies enables the remedies to act directly on the affected parts, and thus ensures a quicker recovery from the external dynamic disease (Rawat, 1996: XLi – XLii). Jouanny (1996:67) states that when the medicinal similarity of the patient is at the level of the local signs, then the homoeopathic similarity is slight. In this situation, a low potency is prescribed. Based on the above principle, two constituents of the complex utilized in this study, namely, *Apis mellifica* and *Urtica urens*, were in the D3 potency. The symptom similarity of these ingredients in relation to the symptom picture of “Athlete’s Foot” will follow under the discussion of each remedy (pg24-25).

2.9.3 POLYPHARMACY

Polypharmacy is a method of prescribing whereby a number of homoeopathic medicines have been combined and prescribed simultaneously. This combination of two or more remedies is referred to as a complex (Tomlinson, 1999: 2).

Complex remedies are prescribed solely on the basis that the remedies have a degree of similarity to the disease process (Watson, 1991:71). The remedies in the complex are chosen because they are partial similars, one covering the symptoms that the other does not (Kayne, 1997:104).

Complex prescribing differs from classical homoeopathic prescribing in that classical homoeopathy makes use of one remedy at a time and that remedy is the similimum. The similimum is the remedy that fits all the symptoms of the disease picture (Kayne, 1997:106). The administration of complexes can be seen as increasing the chance of the correct prescription as it enables the practitioner to treat more than one symptom of the same condition (Kayne, 1997:106).

Complexes consist of remedies in low potencies generally, commonly within the range of \emptyset – 6c, and the prescription is usually repeated on a daily basis (Watson, 1991:71). The decimal potency scale is prepared by adding one drop of mother tincture to nine drops of diluent (alcohol). These potencies are designated by a number followed by the letter 'x' or 'D' (Kayne, 1997:50). Therefore, D3 represents a one in ten dilution that has been carried out three times. The centesimal potency scale is prepared by adding one drop of mother tincture to ninety nine drops of diluent (alcohol). These potencies are designated by a number followed by the letters 'cH'. This refers to the classical method of dilution formulated by Hahnemann (Kayne, 1997:50).

Off-the-shelf complexes, although not classically a very common method of homoeopathic treatment, do have a place in homoeopathy as they provide an

avenue for the general public to become familiar with homoeopathy. This often provides their first experience of homoeopathy during attempts to self-treat common ailments. This first experience leads to consults with qualified homoeopaths where individuals can then receive proper classical homoeopathic treatment (Tomlinson, 1999: 8). Swayne (2000:42) defines classical homoeopathy as a “doctrine or school of homeopathic philosophy and therapeutics claiming to be based on strict Hahnemannian principles.” It is a therapeutic method that makes use of a single medicine in a single prescription (Swayne, 2000:42).

A combination of the following remedies was utilized in the form of a topical application.

ALLIUM SATIVUM (GARLIC)

Allium sativum (Garlic) contains a volatile oil composed of a number of sulphur-containing compounds such as allicin, ajoene, diallyl disulfide and others. Allium sativum has a wide range of pharmacological effects including, antibacterial activity, antiviral effects and antifungal activity (Murray, 1995:121-124).

Ledezma, E., *et al.*, (2000) conducted a double blind and comparative study of ajoene, an organosulphur compound isolated from garlic and Terbinafine in the treatment of short term Tinea pedis. The efficacy of the treatments, measured as mycological cure, 60 days after the end of treatment in 47 patients was 100% for 1% ajoene and 94% for 1% Terbinafine.

De Smidt (2001) used *Allium sativum* *in vitro* on *Candida albicans* with positive results. This study showed that *Candida albicans* was most sensitive to fresh garlic extract, being killed within six hours.

D.S. Arora and J. Kaur (1999) used aqueous garlic extract in a comparative study with Nystatin and found that garlic was far more effective than Nystatin in inhibiting the growth of a variety of bacterial and fungal species.

Garlic is often effective against infectious organisms such as bacteria, viruses and fungi because allicin has the ability to block the action of the enzymes that give these organisms their ability to invade and damage tissues (Anders, *et al.*, 1999:293).

The complex utilized in this study contained *Allium sativum* (Garlic) in mother tincture (Ø). The reason for this was to investigate the antifungal properties of the tincture in the treatment of *Tinea pedis*, which is a superficial fungal infection.

HYDRASTIS CANADENSIS

Hydrastis canadensis (Goldenseal) contains the alkaloids berberine and hydrastine, which give it broad antimicrobial and immune stimulating action.

Berberine has exhibited antibiotic activity against bacteria, protozoa and fungi (Murray, 1995:162-167).

B.Y.Hwang et al (2003) found that berberine exhibited antibacterial activity against the oral pathogen *Streptococcus mutans*.

Budree (2003) used *Hydrastis canadensis in vitro* on *Candida albicans* with positive results. The study showed that Fluconazole was less effective than *Hydrastis canadensis* in inhibiting the *in vitro* growth of *Candida albicans*. *Hydrastis canadensis* tincture is applied topically in the treatment of mouth ulcers as it promotes healing of the mucous membranes (Anders et al., 1999:303).

The complex utilized in this study contained *Hydrastis canadensis* (Goldenseal) in mother tincture (Ø). The reason for this was to investigate the antifungal properties of the tincture in the treatment of *Tinea pedis*, which is a superficial fungal infection.

APIS MELLIFICA

Apis mellifica is indicated in conditions of the skin where there is stinging and burning sensations, with red-pink discolouration and oedema, improvement with cold application and aggravation with warmth. The common factors are the oedema and pruritus improved with cold (Jouanny, *et al.*, 1996:29).

Apis acts on the outer parts, particularly the skin, with redness and marked sensitivity to heat and touch (Boericke, 1998:61).

URTICA URENS

Urtica urens is indicated for itching blotches; burning heat sensation with formication and itching (Boericke, 1998:662).

The skin itches and burns, being aggravated by warmth and bathing, and

relieved by rubbing (Vermeulen, 1992: 404).

This remedy is indicated for oedema with stinging and burning with intolerable itching. The symptoms are aggravated by cold applications and most of all by touch (Jouanny, *et al.*, 1996:208).

Apis mellifica and Urtica urens were selected as part of this complex based on the Law of Similars, as the physical symptoms of both Apis mellifica and Urtica urens are similar to those of “Athlete’s foot”.

The complex utilized in this study is regarded as naturopathic due to the following reasons:

- Two of the four ingredients, namely Allium sativum and Hydrastis canadensis, having each been utilized in mother tincture, were selected for their antifungal properties.
- Apis mellifica and Urtica urens, having each been utilized in homoeopathic potency, namely, D3, were selected according to the law of similars, as has been mentioned.

2.9.4 PLACEBO

Swayne (2000:162) provides two definitions for Placebo:

1. A substance with no active biological properties, knowingly or unknowingly used to exert a beneficial therapeutic effect, or given to satisfy a patient’s expectations of treatment.
2. An inactive agent used for comparison with the substance or method to be

tested in a controlled trial, and indistinguishable from it.

The difference between these two definitions is that one emphasizes the use of placebo as a therapy, whereas, the other focuses on the use of placebo as a neutral control against which a therapy is measured.

“Placebo”, which is Latin for “I shall please”, is a medication or treatment that is believed by the administrator of the treatment to be inert. The active ingredient is therefore absent. The placebo effect is the measurable, observable or perceived improvement in health that is not attributable to treatment (Carroll, 2002).

Carroll (2000) highlights the three current theories on Placebo:

- **The psychological theory: it's all in your mind:**

This theory suggests that the placebo effect is psychological, due to a belief in the treatment or due to a subjective feeling of improvement. A person's beliefs and hopes about a treatment may have a significant biochemical effect. Thoughts and sensory experience can affect the body's neurochemical system, which can in turn affect the hormonal and immune systems, thus providing a feeling of well being.

- **The nature-taking-its-course theory:**

This theory suggests that the placebo effect is due to an illness or injury taking its course. Individuals do often heal spontaneously without doing anything to treat their illness. There are however, situations where individuals who are not given treatment at all, do not do as well as those who are given

placebos or real medicine.

- **The process-of-treatment theory:**

This theory suggests that a process that is encouraging and hopeful, that is, showing a patient attention, care and affection, may trigger physical reactions in the body, which promote healing. This process is thought to reduce stress, which slows down or prevents further physical changes from occurring.

This evidence suggests that there are various factors that can influence the action of a placebo, and that these factors should be taken into consideration in a clinical trial.

CHAPTER THREE

MATERIALS AND METHODS

3.1 THE OBJECTIVE / PROBLEM STATEMENT

This study proposed to evaluate the efficacy of a topical naturopathic complex in the treatment of Tinea pedis with regards to the visible improvement of the condition of the feet. It focused on participants between the ages of eighteen and sixty.

The objective is to assess the role that this treatment has to play in the management of this condition.

3.2 THE DATA

Primary and secondary data were used in this study. The primary data is represented by the degree of visible improvement or absence thereof, of the condition of the feet, as well as the patient's perception of the treatment over a period of 28 days.

The secondary data was obtained from the available literature on Tinea pedis, as well as information sourced from the Internet.

3.3 THE RESEARCH METHODOLOGY

3.3.1 RESEARCH DESIGN

The research comprised of a clinical trial that was conducted over a twenty-eight day period. Each patient therefore received treatment for a period of one month. Participants were recruited through advertising. Advertisements were placed on

notice boards at the Durban Institute of Technology, pharmacies, and health shops, libraries and in newspapers.

3.3.2 SUBJECTS

The subjects for this research were obtained through advertisements placed on campus notice boards, libraries and newspapers in the greater Durban area. All subjects had to meet the inclusion criteria (see pg 29).

3.3.3 SAMPLE

Thirty subjects participated in this trial. Subjects were selected for this study using convenience sampling, based on the inclusion and exclusion criteria stated below. Sixteen people received the placebo cream and fifteen people received the treatment cream. Subjects who agreed to participate in the study were given an information form (see Appendix B). Patients were assessed according to the selection criteria. Those who met the selection / inclusion criteria were required to sign an informed consent form (see Appendix C1) and a patient details form (see Appendix C2).

3.3.4 INCLUSION CRITERIA

Participants were selected if they met the following criteria:

- Participants had to be between the ages of 18 and 60 years;
- Both sexes were accepted;
- Participants had to have two or more of the signs and symptoms of “Athlete’s foot”, namely, cracking and peeling of the skin, usually in the

spaces between the fourth and fifth toes; redness; drying; itching and burning of the skin (Fitzpatrick, *et al.* 1992).

- Participants were not to be on any treatment (alternative or allopathic) for “Athlete’s foot”, for a week prior to the commencement and for the duration of the trial.

3.3.5 EXCLUSION CRITERIA

Potential participants were excluded based on the following criteria:

- Patients who were on current medication (allopathic or alternative) for their “Athlete’s foot”;
- Diabetic patients, especially those with poorly managed, longstanding diabetes, due to the possibility of complicating infections;
- Pregnant or lactating females;
- Patients with a history of Hypertension;
- Patients with any skin disease;
- Patients with any history of allergic responses to creams, soaps or any other topical applications and allergies such as bee stings, wasp stings etc.

3.4 EXPERIMENTAL DESIGN AND PROCEDURE

3.4.1 INTERVIEW AND CONSULTATION

At the beginning of the first consultation the aims and objectives, the treatment, physical examination procedures and trial design were explained to each

potential participant. Those who agreed to participate were then requested to sign a consent form (Appendix C1) and a Patient details form (Appendix C2). A brief case history (Appendix F) was taken to ensure that patients met the inclusion criteria and this was followed by a physical examination of the feet (Appendix G). During the physical examination the feet were thoroughly examined by the researcher for the signs of Tinea pedis. The clinician on duty was then called in to examine the participant's feet. Both the clinician and researcher then rated the degree of severity of the signs present according to the Visual scale (see Appendix E). The rating of the severity of the signs of Tinea pedis on each participant's feet was carried out in the first and again in the 3rd / final consultation. The condition of the participant's feet in the first consult therefore served as the baseline against which improvement was measured at the third and final consultation on the twenty eighth day of the trial. Improvement of the condition of the feet was also established with the aid of the Patient perception questionnaire (Appendix D), which was to be completed by the participant during all three consultations.

The second consultation (first follow up) which took place two weeks after the initial consultation was a brief consult which was aimed at monitoring patient compliance. During this consultation the physical examination was completed and the feet particularly examined to note the progress or lack thereof being made. The participant was once again requested to complete the Patient perception questionnaire (Appendix D).

The final consultation took place two weeks after the second consult. During this consult the physical examination was once again completed. The feet were examined as in the first consult by both the clinician and the researcher and rated according to the visual scale (Appendix E). The participant had to complete the Patient perception questionnaire.

3.4.2 THE PROCESS OF RANDOMISATION

Thirty participants were randomly assigned to the placebo (sixteen) and treatment (fifteen) groups.

Randomization was conducted by the clinic secretary (Department of Homoeopathy, Durban Institute of Technology). The treatment and placebo creams were labelled with identifying barcodes and the medication was dispensed to the respective groups according to the randomization sheet.

Randomization was carried out in order to ensure the double blind nature of the trial. Since this was a double blind study, the researcher knew the identity of the participants, but was unaware as to who was part of the placebo group and treatment group respectively. Similarly, the participants were aware of the presence of the placebo group, but were unaware as to which group they were being placed into.

3.4.3 THE MEDICINE

The medicine was prepared by Natura Homoeopathic Laboratories (a registered homoeopharmaceutical company) of the quality and according to the standards set out in the German Homoeopathic Pharmacopoeia.

The experimental medicine consisted of an aqueous cream base impregnated at a 10% volume-to-volume concentration with an ethanol-based complex comprising of equal parts of *Allium sativum* Ø; *Apis mellifica* D3; *Hydrastis canadensis* Ø and *urtica urens* D3. The amount of treatment cream provided was 140ml.

The placebo consisted of an aqueous cream base impregnated at a 10% volume-to-volume concentration with plain ethanol. The amount of placebo cream provided was 140ml.

The treatment cream and the placebo cream were both impregnated with an inert colorant to make the creams indistinguishable.

3.4.4 THE TREATMENT

The medication was provided at the first consultation. The amount of cream provided for both treatment and placebo was 140ml and was to last four weeks (27days). 5ml plastic spoons were provided to the participants to dispense the cream. Each participant was to measure out exactly 5ml (a level teaspoon) of cream. This amount was to be divided equally (approximately 2.5ml) between both feet and applied evenly throughout both feet.

Participants were instructed to apply the cream once a day, in the evenings before bed, after having washed and dried the feet properly. This was done to allow the medicine sufficient time to work while the body was resting during the night.

3.4.5 DOUBLE BLIND

This was a placebo controlled, double blind and randomized trial. Tinea pedis is not a life threatening condition, nor were the participants currently being treated. The patients participating in this trial were informed of the possibility that they may receive placebo before the trial began. Having taken this into consideration, the researcher considered it ethically acceptable to use a placebo group as a measure against which treatment could be compared. At the completion of the study, those that received placebo were notified and offered free treatment.

3.4.6 MEASUREMENTS

The Patient Perception Questionnaire (Appendix D) and the Visual Scale for the Assessment of the Feet (Appendix E) were utilized as measurement tools. The Visual Scale for the Assessment of the Feet was completed in the first and last consults respectively. This scale measured the signs of tinea pedis, namely, red blotches, cracked skin, dryness, peeling and bleeding. Each of the fore mentioned signs were rated on a 5-point scale (1=very severe, 2=severe, 3=moderately severe, 4=slight, 5=absent). The scores for each lesion were summed and the average was calculated before (first consult) and after (last consult) treatment. The researcher and an independent 3rd party (the attending clinician) performed the Visual Assessment.

The subjects assessed their own signs and symptoms, and their response to the treatment they were receiving, using the Patient Perception Questionnaire. The

questionnaire was completed throughout treatment in the 1st, 2nd and 3rd consultations. In the 1st consult, only Q1; Q4; Q5 and Q8 were answered as they related to the current condition of the patient's feet. Q2; Q3; Q6; Q7 and Q9 were not answered in the 1st consult as they related to the change in the condition of the feet during treatment. Thereafter all questions were answered in the 2nd and 3rd consultations.

At the end of the study, the data was collated, analyzed and interpreted by means of statistical methods.

3.4.7 DATA ANALYSIS

Statistical analysis was conducted using the SPSS (Version 13) software Suite. This statistical software program was manufactured by SPSS Inc, 444n. Michigan Avenue, Chicago, Illinois, USA. Various descriptive and inferential statistical techniques were used. The descriptive procedures used were various tables, including Frequency tables, and graphs and a few summary statistics including but not limited to means, proportions and percentages. Inferential statistics included various hypothesis-testing techniques. Due to the size of the samples, namely 15 in the treatment group and 16 in the placebo group, non-parametric statistical tests were used. Type 1 error was set as 5% for all tests, or mentioned differently, $\alpha = 0.05$. If the P value was reported as less than 0.05 a significant result was to be declared and the null hypothesis was to be rejected.

3.4.7.1 Procedure 1: (Intra tests for both treatment and placebo groups)

Wilcoxon's Signed Rank Test

The Wilcoxon's signed rank test was conducted based on ratings from the Patient perception questionnaire (PPQ) (Appendix D) and the Visual scale for the assessment of appearance (VS) (Appendix E). It tested for a significant difference in population means between readings within the Treatment Group and the Placebo Group.

i. Hypothesis testing

The null hypothesis H_0 , states that there is no significant difference between the three consultations being compared at the $\alpha = 0.05$ level of significance.

The alternative hypothesis H_1 , states that there is a significant difference between the three visits being compared.

ii. Decision rule

At the $\alpha = 0.05$ level of significance, the null hypothesis is rejected if $p \leq \alpha$, where p is the observed significance level. Otherwise the null hypothesis is accepted at the same level of significance.

Frequencies

Frequency tables were utilized for readings taken from the Patient perception questionnaire. The tables were used for questions 2, 2.1, 3, 6, 7 and 8 specifically. This was done because the questions related to changes in signs and symptoms experienced during treatment, which only became applicable in the 2nd and final consultations. Readings were taken from consultations two

and three for both the Treatment and Placebo groups. Each question had an answer choice ranging from a scale of 1 to 5 (with 1 being the worst and 5 being the best). The frequency tables focused on how frequently each answer choice was selected by participants for each question.

3.4.7.2 Procedure 2: (Inter tests between both groups)

Kruskal Wallis Test

The inter-group analysis was done using the Kruskal Wallis test. The Treatment and Placebo groups were compared to each other using ratings taken from the PPQ (Appendix D) and the VS (Appendix E).

The two groups were compared to each other (using PPQ readings) with regards to analysis of questions 1,4,5,8 during all three consultations. Inter-group analysis of VS readings (which were taken during the 1st and last consultations) was also conducted.

I. Hypothesis testing

The null hypothesis H_0 , states that there is no significant difference between the three consultations (for the PPQ) and the 1st and last consultation (for the VS) being compared at the $\alpha = 0.05$ level of significance. The alternative hypothesis H_1 , states that there is a significant difference between the three consultations (for the PPQ) and the 1st and last consultation (for the VS) being compared.

II. Decision rule

At the $\alpha = 0.05$ level of significance, the null hypothesis is rejected if $p \leq \alpha$, where p is the observed significance level. Otherwise the null hypothesis is accepted at the same level of significance.

CHAPTER FOUR

RESULTS

4.1 INTRODUCTION

This chapter contains the results obtained from the statistical analysis of the data collected from the two groups used in this trial.

The Wilcoxon's Signed Rank Test was used to determine if there was a significant difference in population means within each group.

H_0 : There is no difference after treatment

H_1 : There is a significant difference after treatment

In each case α was set at 0.05 (specified level of significance). H_0 was rejected if $P < \alpha$ and vice versa.

The Kruskal Wallis Test was used to determine if any of the groups were statistically more significant than the other.

H_0 : There is no difference after treatment

H_1 : There is a significant difference after treatment

In each case α was set at 0.05 (specified level of significance). H_0 was rejected if $P < \alpha$ and vice versa.

4.2 CRITERIA GOVERNING THE ADMISSIBILITY OF THE DATA

Only data obtained from the Patient Perception Questionnaires and the Visual Scale for the Assessment of the Feet, which were completed during the trial,

were used for statistical analysis. The questionnaires were completed by the participants in all three consultations and the visual scale was completed by the researcher and the attending clinician at the 1st and last consultations.

4.2.1 DEMOGRAPHIC DATA

As can be seen from Figure 4.1, more males than females participated in this study. Out of the total of thirty one participants, seventeen participants were male and fourteen were female.

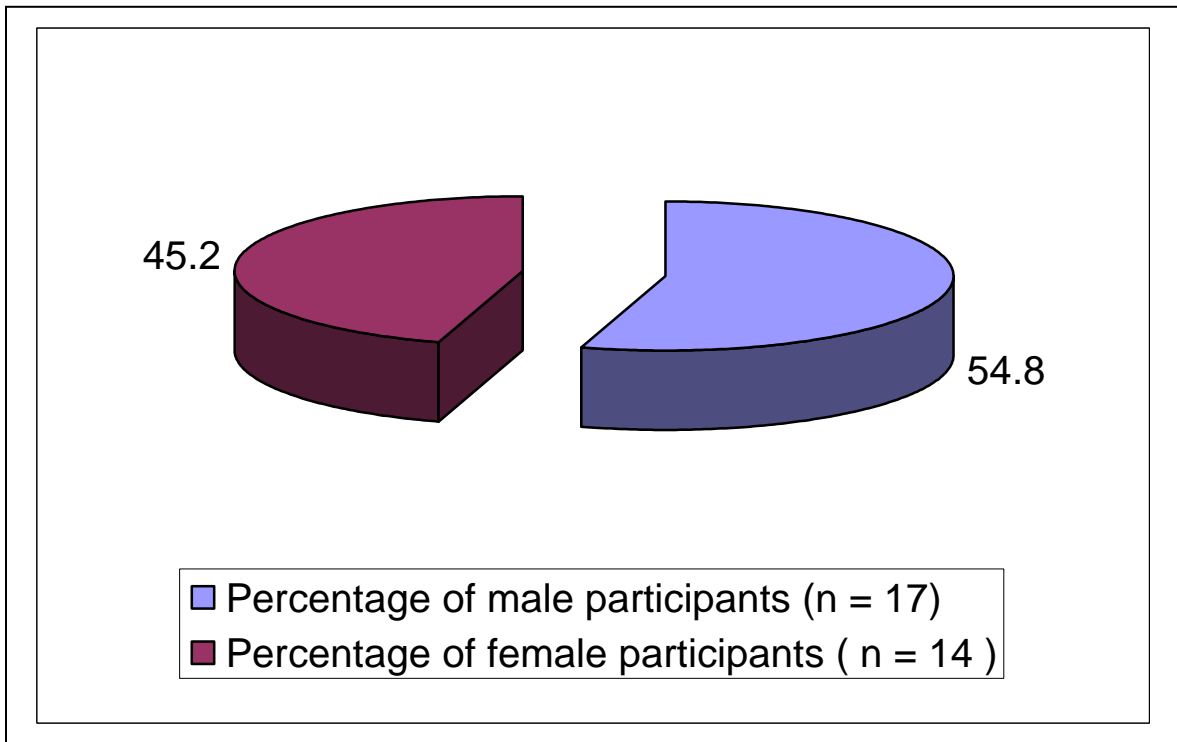


Figure 4.1 Pie - chart showing the percentage of male & female participants

4.2.2 BARGRAPHS REPRESENTING THE COMPARISON BETWEEN THE MEANS OF THE VISUAL SCALE FOR TREATMENT AND PLACEBO GROUPS

Figure 4.2 represents the comparison between the means of Visual Scale scores for 'Red Blotches' for Group 1 (Treatment) and Group 2 (Placebo), before (consult 1) and after (consult 3) treatment.

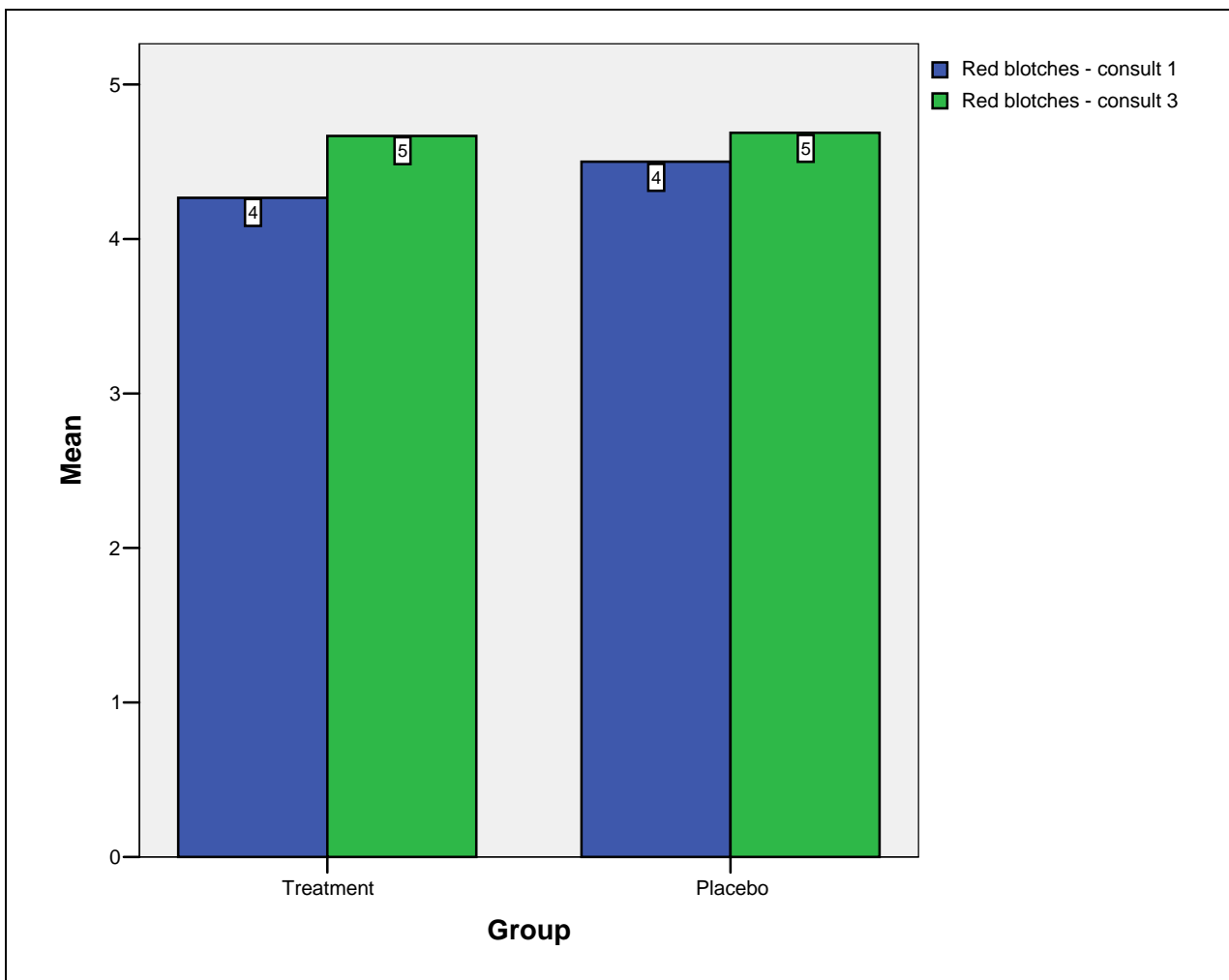


Figure 4.2 Barchart showing Visual scale scores for red blotches before and after treatment

Figure 4.3 represents the comparison between the means of Visual Scale scores for 'Cracked skin' for Group 1 (Treatment) and Group 2 (Placebo), before (consult 1) and after (consult 3) treatment.

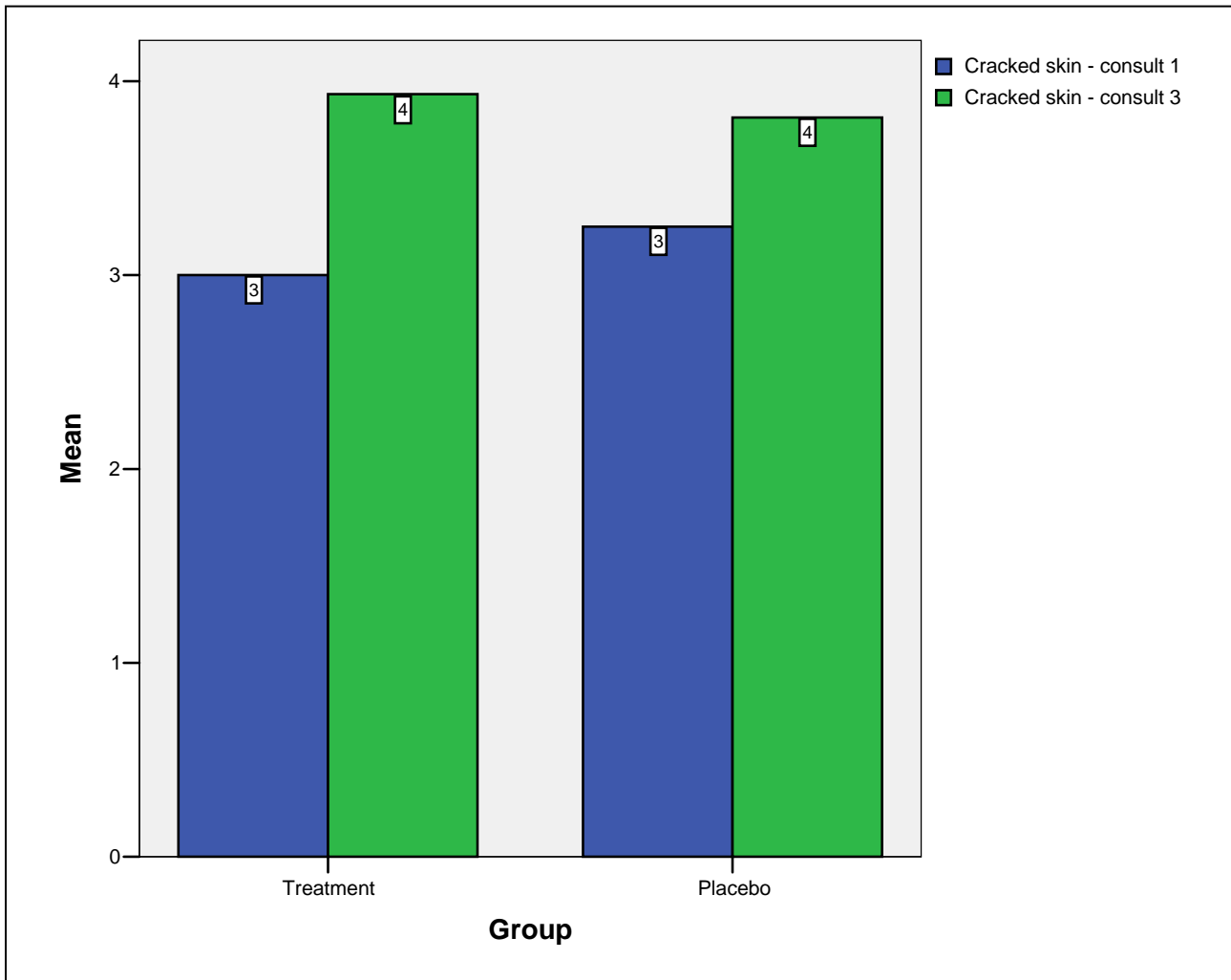


Figure 4.3 Barchart showing Visual scale scores for cracked skin before and after treatment

Figure 4.4 represents the comparison between the means of Visual Scale scores for 'Dry skin' for Group 1 (Treatment) and Group 2 (Placebo), before (consult 1) and after (consult 3) treatment.

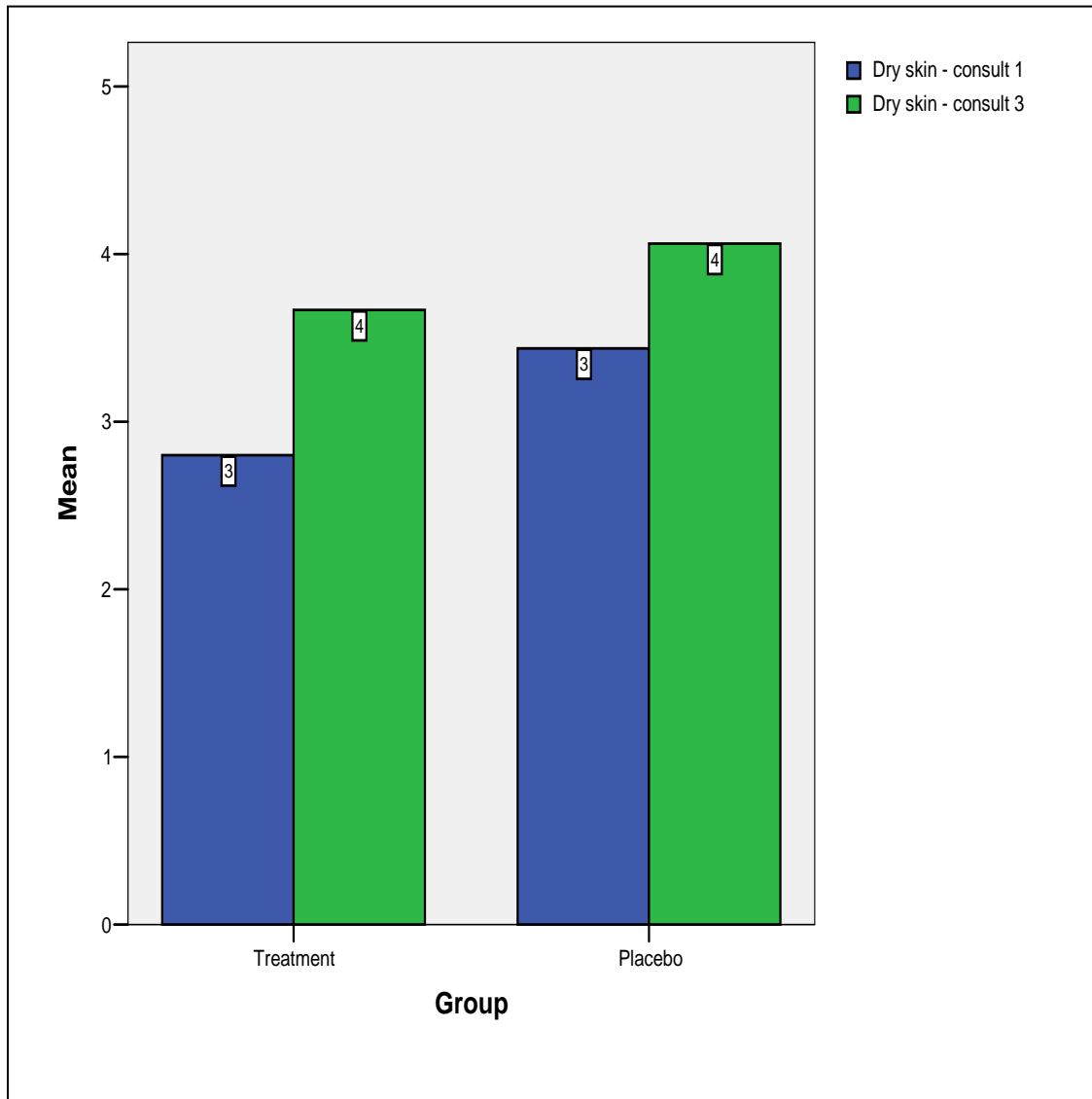


Figure 4.4 Barchart showing Visual scale scores for dry skin before and after treatment

Figure 4.5 represents the comparison between the means of Visual Scale scores for 'Peeling skin' for Group 1 (Treatment) and Group 2 (Placebo), before (consult 1) and after (consult 3) treatment.

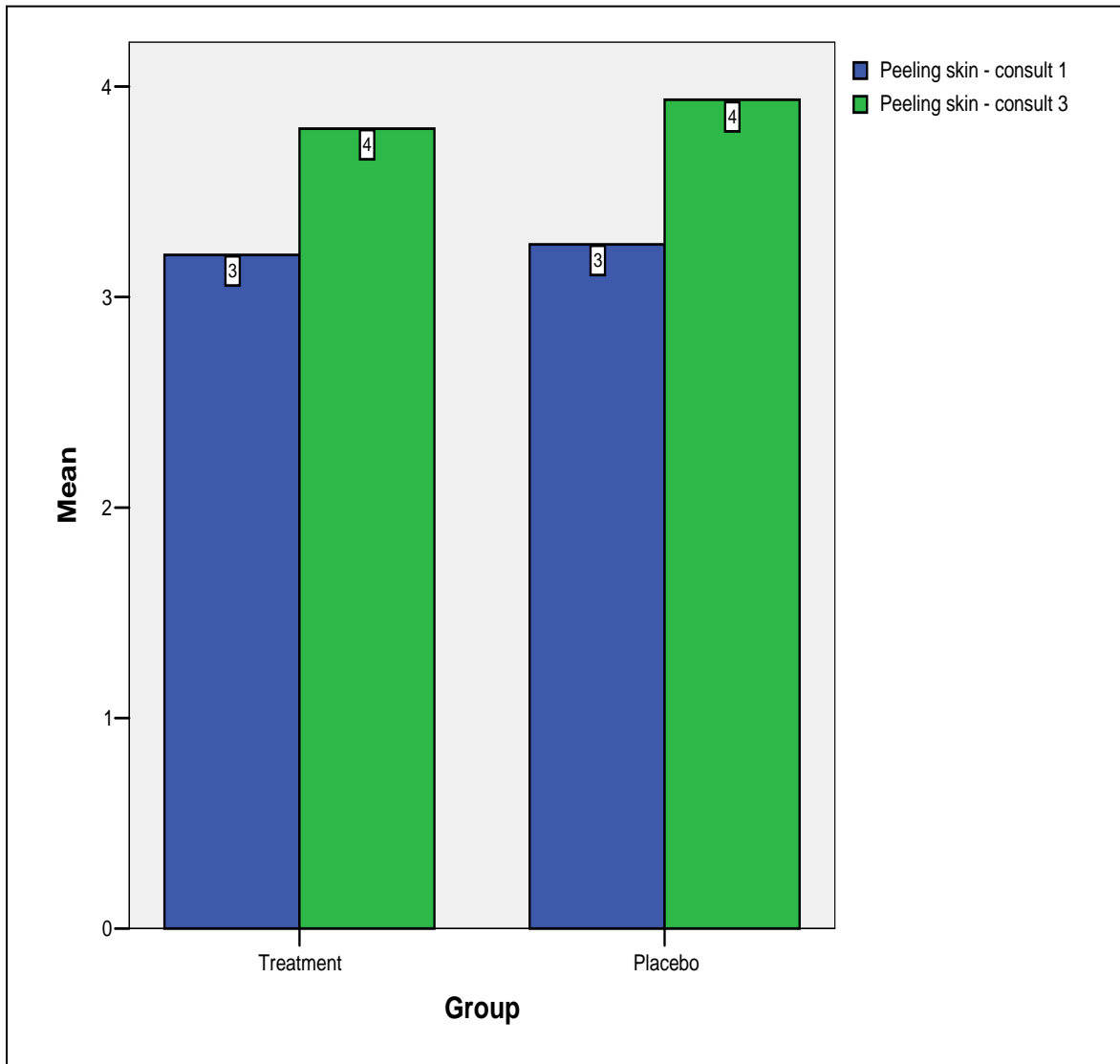


Figure 4.5 Barchart showing Visual scale scores for peeling skin before and after treatment

Figure 4.6 represents the comparison between the means of Visual Scale scores for 'bleeding skin' for Group 1 (Treatment) and Group 2 (Placebo), before (consult 1) and after (consult 3) treatment.

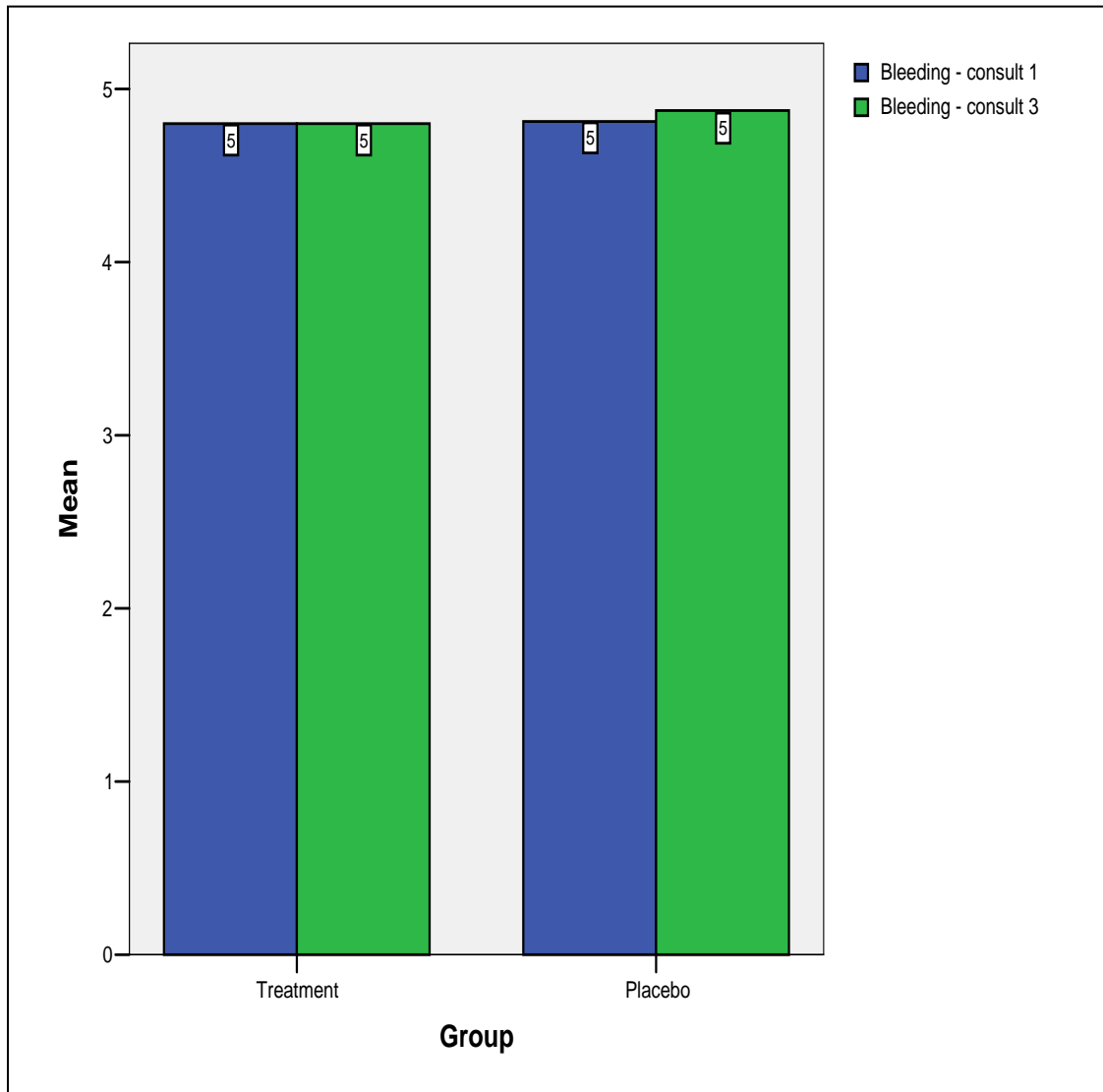


Figure 4.6 Barchart showing Visual scale scores for bleeding skin before and after treatment

4.3 STATISTICAL ANALYSIS

4.3.1 PROCEDURE 1 (INTRA-GROUP COMPARISON):

WILCOXON'S SIGNED RANK TEST

4.3.1.1 PATIENT PERCEPTION QUESTIONNAIRE (PPQ) (APPENDIX D) –

Wilcoxon's Signed Rank Test

Table 4.1 Comparison within each group between consults 2 and 1, consults 3 and 2, and, consults 3 and 1 respectively

Group	Q1			Q4			Q5			Q8		
	C2-C1	C3-C2	C3-C1	C2-C1	C3-C2	C3-C1	C2-C1	C3-C2	C3-C1	C2-C1	C3-C2	C3-C1
Treatment (P value)	.019*	.084	.004*	.014*	.416	.004*	.050	.054	.005*	.006*	1.000	.006*
Placebo (P value)	.003*	.483	.003*	.002*	.084	.001*	.003*	.230	.002*	.030*	1.000	.008*

Table 4.1 reveals the following:

Treatment group:

- At the 2nd consultation of the trial, there were significant differences ($p < 0.05$) for Questions 1, 4 and 8 (3 of the 4 variables).
- At the final consultation of the trial, there were significant differences for questions 1, 4, 5 and 8 (4 out of the 4 variables).

Placebo group:

- At the 2nd consultation of the trial, there were significant differences ($p < 0.05$) for questions 1, 4, 5 and 8 (4 out of 4 variables).
- At the final consultation of the trial, there were significant differences for questions 1, 4, 5 and 8 (4 out of the 4 variables).

4.3.1.2 FREQUENCY TABLES FOR THE PPQ

Q2 'Has your "Athlete's foot" changed at all since treatment?'

Table 4.2 (A) Treatment Group

	Consult 2		Consult 3	
	Frequency	Percentage	Frequency	Percentage
1 not at all	1	6.7	1	6.7
2 very slightly	2	13.3	1	6.7
3 slightly	4	26.7	2	13.3
4 moderately	5	33.3	5	33.3
5 very much	3	20.0	6	40.0
TOTAL	15	100.0	15	100.0

The following can be observed from Table 4.2(A)

For the treatment group:

At consult 2 (14 days of treatment):

- 14 out of 15 participants (93.3%) showed a change in their condition ranging from '2-very slightly' to '5-very much'.
- Only 1 out of 15 participants (6.7%) reported no change in their condition.

At consult 3 (28 days of treatment):

- 6 out of 15 participants (40.0%) rated their condition as 5 (having changed 'very much'), as compared to consult 2 where only 3 out of 15 participants (20.0%) rated their condition as 5 (having changed 'very much').

Q2 'Has your "Athlete's foot" changed at all since treatment?'

Table 4.2 (B) Placebo Group

	Consult 2		Consult 3	
	Frequency	Percentage	Frequency	Percentage
1 not at all	1	6.3	1	6.3
2 very slightly	4	25.0	2	12.5
3 slightly	2	12.5	1	6.3
4 moderately	5	31.3	2	12.5
5 very much	4	25.0	10	62.5
TOTAL	16	100.0	16	100.0

The following can be observed from Table 4.2(B)

For the placebo group:

At consult 2 (14 days of treatment):

- 15 out of 16 patients (93.7%) in the placebo group reported a change in their condition ranging from '2- very slightly' to '5- very much'.
- Only 1 out of 16 participants (6.3%) reported no change.

At consult 3 (28 days of treatment):

- 10 out of 16 participants (62.5%) rated their condition as 5 (having changed 'very much'), as compared to consult 2 where only 4 out of 16 participants (25.0%) rated their condition as 5 (having changed 'very much').
- 1 participant (6.3%) reported no change.

Q2.1 'If your "Athlete's foot" has changed, how has it changed?'

Table 4.3 (A) Treatment Group

	Consult 2		Consult 3	
	Frequency	Percentage	Frequency	Percentage
1 getting worse	1	6.7	-	-
2 getting slightly better	5	33.3	2	13.3
3 getting better	5	33.3	5	33.3
4 Getting much better	3	20.0	5	33.3
5 has completely gone	-	-	2	13.3
TOTAL	14	93.3	14	93.3

The following can be observed from Table 4.3(A)

For the treatment group:

At consult 2 (14 days of treatment):

- 14 out of 15 patients in the treatment group who noticed a change, reported a change ranging from '1-getting worse' to '4-getting much better'.
- Only 1 patient reported no change ('not at all') (see also Table 4.2 (A)).

At consult 3 (28 days of treatment):

- 5 out of 15 participants reported a change of '4-getting much better' as compared to 3 participants in consult 2.
- 2 participants said that their 'Athlete's foot' had 'completely gone' (5).
- 1 out of the 15 participants reported no change (see also Table 4.2 (A)).

Q2.1 'If your "Athlete's foot" has changed, how has it changed?'

Table 4.3 (B) Placebo group

	Consult 2		Consult 3	
	Frequency	Percentage	Frequency	Percentage
1 getting worse	2	12.5	-	-
2 getting slightly better	4	25.0	2	12.5
3 getting better	3	18.8	4	25.0
4 getting much better	6	37.5	6	37.5
5 has completely gone	1	6.3	3	18.8
TOTAL	16	100.0	15	93.8

The following can be observed from Table 4.3 (B)

For the placebo group:

At consult 2 (14 days of treatment):

- 16 out of 16 patients (100.0%) in the placebo group reported a change ranging from '1-getting worse' to '5-has completely gone'.
- 2 participants (12.5%) reported that their "Athlete's foot" was 'getting worse' (1).
- 4 participants (25.0%) reported that their "Athlete's foot" was 'getting slightly better' (2).

- 3 participants (18.8%) reported that their “Athlete’s foot” was ‘getting better’ (3).
- 6 participants (37.5%) reported that their “Athlete’s foot” was ‘getting much better’ (4).
- 1 participant (6.3%) reported that their “Athlete’s foot” had ‘completely gone’ (5).

At consult 3 (28 days of treatment):

- 15 out of 16 participants reported a change in their condition ranging from ‘2-getting slightly better’ to ‘5-has completely gone’.
- 3 participants said that their “Athlete’s foot” had ‘completely gone’ (5), as compared to 1 participant in consult 2.
- 1 out of the 16 participants (6.3%) reported no change (see Table 4.2 (B)).

Q3 'Has the appearance of your feet changed?'

Table 4.4 (A) Treatment group

	Consult 2		Consult 3	
	Frequency	Percentage	Frequency	Percentage
1 not at all	2	13.3	1	6.7
2 very slightly	3	20.0	2	13.3
3 slightly	4	26.7	4	26.7
4 moderately	4	26.7	3	20.0
5 very much	2	13.3	5	33.3
TOTAL	15	100.0	15	100.0

The following can be observed from Table 4.4 (A)

For the treatment group:

At consult 2 (14 days of treatment):

- 13 out of 15 participants (86.7%) noted a change in the appearance of their feet ranging from '2-very slightly' to '5-very much'.
- 2 out of the 15 participants (13.3%) reported no change in the appearance of their feet.

At consult 3 (28 days of treatment):

- 14 out of 15 participants (93.3%) noted a change in the appearance of their feet ranging from '2-very slightly' to '5-very much'.
- Only 1 participant (6.7%) reported no change in the appearance of the feet.

Q3 'Has the appearance of your feet changed?'

Table 4.4 (B) Placebo group

	Consult 2		Consult 3	
	Frequency	Percentage	Frequency	Percentage
1 not at all	-	-	2	12.5
2 very slightly	6	37.5	-	-
3 slightly	2	12.5	3	18.8
4 moderately	4	25.0	5	31.3
5 very much	4	25.0	6	37.5
TOTAL	16	100.0	16	100.0

The following can be observed Table 4.4 (B)

For the placebo group:

At consult 2 (14 days of treatment):

- All 16 participants (100.0%) noted a change in the appearance of the feet ranging from '2-very slightly' to '5-very much'.
- 6 participants (37.5%) reported that the appearance of their feet had changed 'very slightly' (2).
- 2 participants (12.5%) reported that the appearance of their feet had changed 'slightly' (3).
- 4 participants (25.0%) reported that the appearance of their feet had changed 'moderately' (4).
- 4 participants (25.0%) reported that the appearance of their feet had

changed 'very much' (5).

At consult 3 (28 days of treatment):

- 14 out of 16 participants (87.5%) reported a change in the appearance of their feet ranging from '3-slightly' to '5-very much'.
- 3 participants (18.8%) reported that the appearance of their feet had changed 'slightly' (3).
- 5 participants (31.3%) reported that the appearance of their feet had changed 'moderately' (4).
- 6 participants (37.5%) reported that the appearance of their feet had changed 'very much' (5).
- 2 participants (12.5%) reported no change in the appearance of the feet.

Q6 'Has the surface texture of your skin changed?'

Table 4.5 (A) Treatment group

	Consult 2		Consult 3	
	Frequency	Percentage	Frequency	Frequency
1 become much rougher	1	6.7	-	-
2 rougher	1	6.7	1	6.7
3 slightly smoother	7	46.7	7	46.7
4 smoother	4	26.7	2	13.3
5 much smoother	1	6.7	5	33.3
TOTAL	14	93.3	15	100.0

The following can be observed from Table 4.5 (A)

For the treatment group:

At consult 2 (14 days of treatment):

- 12 out of 15 participants (80.1%) in the treatment group noticed the surface texture of their feet become smoother (ranging from '3-slightly smoother' to '5-much smoother').
- 1 participant noticed their feet to have become 'rougher' (2) after 14 days.
- 2 participants noted no change in the surface texture of their feet (Table 4.2A).

At consult 3 (28 days of treatment):

- 1 participant (6.7%) reported that the feet had become 'rougher' (2).
- 5 participants (33.3%) had reported that the feet had become 'much smoother' at consult 3 as compared to only 1 participant (6.7%) at consult 2.

Q6 'Has the surface texture of your skin changed?'

Table 4.5 (B) Placebo group

	Consult 2		Consult 3	
	Frequency	Percentage	Frequency	Percentage
1 become much rougher	-	-	-	-
2 rougher	2	12.5	2	12.5
3 slightly smoother	5	31.3	3	18.8
4 smoother	6	37.5	6	37.5
5 much smoother	3	18.8	5	31.3
TOTAL	16	100.0	16	100.0

The following can be observed from Table 4.5 (B)

For the placebo group:

At consult 2 (14 days of treatment):

- All 16 participants in the placebo group reported a change in surface texture ranging from '2-rougher' to '5-much smoother'.
- 2 participants (12.5%) reported that their skin had become 'rougher' (2).
- 5 participants (31.3%) reported that their skin had become 'slightly smoother' (3).
- 6 participants (37.5%) reported that their skin had become 'smoother' (4).
- 3 participants (18.8%) reported that their skin had become 'much smoother' (5).

At consult 3 (28 days of treatment):

- All 16 participants reported a change in surface texture ranging from '2-rougher' to '5-much smoother'.
- 5 participants in consult 3 reported the surface texture of the skin to have become '5-much smoother' as compared to 3 participants in consult 2.

Q7 'Has the peeling of your skin improved?'

Table 4.6 (A) Treatment group

	Consult 2		Consult 3	
	Frequency	Percentage	Frequency	Percentage
1 not at all	2	13.3	1	6.7
2 improved slightly	5	33.3	1	6.7
3 improved moderately	5	33.3	5	33.3
4 improved greatly	2	13.3	5	33.3
5 no peeling present	1	6.7	3	20.0
TOTAL	15	100.0	15	100.0

The following can be observed from Table 4.6 (A)

For the treatment group:

At consult 2 (14 days of treatment):

- 13 out of the 15 participants (86.7%) in the treatment group found an improvement in peeling of the feet ranging from '2-improved slightly' to '5-absence of peeling'.
- 2 participants (13.3%) found no improvement in peeling.

At consult 3 (28 days of treatment):

- 14 out of the 15 participants (93.3%) found an improvement in peeling of the feet ranging from '2-improved slightly' to '5-absence of peeling'.
- 3 participants reported the absence of peeling (5-no peeling present) at consult 3 as compared to only 1 participant at consult 2.
- 1 participant (6.7%) found no improvement in peeling at consult 3.

Q7 'Has the peeling of your skin improved?'

Table 4.6 (B) Placebo group

	Consult 2		Consult 3	
	Frequency	Percentage	Frequency	Percentage
1 not at all	1	6.3	3	18.8
2 improved slightly	7	43.8	1	6.3
3 improved moderately	3	18.8	2	12.5
4 improved greatly	3	18.8	6	37.5
5 no peeling present	2	12.5	4	25.0
TOTAL	16	100.0	16	100.0

The following can be observed from Table 4.6 (B)

For the placebo group:

At consult 2 (14 days of treatment):

- 15 out of 16 participants (93.7%) noted an improvement in peeling of the skin ranging from '2-improved slightly' to '5-no peeling present'.
- 1 participant reported no improvement in peeling.

At consult 3 (28 days of treatment):

- 13 out of 16 participants (81.2%) reported an improvement in peeling of the skin ranging from '2-improved slightly' to '5-no peeling present'.
- 3 participants (18.8%) reported no improvement in peeling.
- 4 participants (25.0%) reported the absence of peeling in the 3rd consult as compared to 2 participants (12.5%) in the 2nd consult.

Q9 ‘How do you perceive the treatment to be thus far?’

Table 4.7 (A) Treatment group

	Consult 2		Consult 3	
	Frequency	Percentage	Frequency	Percentage
1 not good at all	-	-	-	-
2 fair	2	13.3	2	13.3
3 satisfactory	3	20.0	2	13.3
4 good	6	40.0	7	46.7
5 excellent	4	26.7	4	26.7
TOTAL	15	100.0	15	100.0

Table 4.7 (A) for the treatment group shows the following:

At consult 2 (14 days of treatment):

Out of 15 participants:

- 2 participants (13.3%) found the treatment to be ‘fair’.
- 3 participants (20.0%) found the treatment to be ‘satisfactory’.
- 6 participants (40.0%) found the treatment to be ‘good’.
- 4 participants (26.7%) found the treatment to be ‘excellent’.

At consult 3 (28 days of treatment):

Out of 15 participants:

- 2 participants (13.3%) found the treatment to be 'fair'.
- 2 participants (13.3%) found the treatment to be 'satisfactory'.
- 7 participants (46.7%) found the treatment to be 'good'.
- 4 participants (26.7%) found the treatment to be 'excellent'.

Q9 'How do you perceive the treatment to be thus far?'

Table 4.7 (B) Placebo group

	Consult 2		Consult 3	
	Frequency	Percentage	Frequency	Percentage
1 not good at all	1	6.3	1	6.3
2 fair	4	25.0	1	6.3
3 satisfactory	-	-	1	6.3
4 good	7	43.8	5	31.3
5 excellent	4	25.0	8	50.0
TOTAL	16	100.0	16	100.0

Table 4.7 (B) for the placebo group shows the following:

At consult 2 (14 days of treatment):

Out of 16 participants:

- 1 participant (6.3%) found the treatment to be 'not good at all'.
- 4 participants (25.0%) found the treatment to be 'fair'.
- 7 participants (43.8%) found the treatment to be 'good'.
- 4 participants (25.0%) found the treatment to be 'excellent'.

At consult 3 (28 days of treatment):

Out of 16 participants:

- 1 participant (6.3%) found the treatment to be 'not good at all'.
- 1 participant (6.3%) found the treatment to be 'fair'.
- 1 participant (6.3%) found the treatment to be 'satisfactory'.
- 5 participants (31.3%) found the treatment to be 'good'.
- 8 participants (50.0%) found the treatment to be 'excellent'.

4.3.1.3 VISUAL SCALE FOR ASSESSMENT OF APPEARANCE OF FEET (VS)

(APPENDIX E) – Wilcoxon’s Signed Rank Test

Table 4.8 Comparison within each group between the first and final consultations

Group	Red Blotches	Cracked skin	Dry skin	Peeling skin	Bleeding skin	VS Ave (total score/5)
Treatment (P value)	.058	.012*	.004*	.007*	1.000	.002*
Placebo (P value)	.429	.025*	.054	.008*	.317	.003*

Table 4.8 reveals the following for the 2 groups:

Treatment group: There were significant differences ($p < 0.05$) for cracked, dry and peeling skin. There was a significant difference ($p < 0.05$) for the total average score in visible improvement of the feet.

Placebo group: There were significant differences ($p < 0.05$) for cracked and peeling skin. There was a significant difference ($p < 0.05$) for the total average score in visible improvement of the feet.

4.3.2 PROCEDURE 2 (INTER-GROUP COMPARISON):

KRUSKAL WALLIS TEST

4.3.2.1 PATIENT PERCEPTION QUESTIONNAIRE (PPQ) (APPENDIX D) –

Kruskal Wallis Test

Table 4.9 Inter-group comparisons for all three consultations

	Consult 1	Consult 2	Consult 3
Q1	.201	1.001	.101
Q4	.424	.492	2.032
Q5	.026*	.141	.019*
Q8	.603	.215	.008*

*: Significant values

The inter-group analysis by means of the Kruskal Wallis Test was conducted in order to see if there was a significant difference between the results of the treatment group and the placebo group, with regard to questions 1; 4; 5 and 8 of the PPQ.

At the $\alpha = 0.05$ level of significance, the tests revealed the following:

A significant difference was noted for Q5 (“rate the burning sensation of your skin’) at consult 3 when treatment was compared to placebo:

P=0.019

$\alpha = 0.05$

The P-value < 0.05 therefore the alternative hypothesis (H_1) was accepted and

the null hypothesis (H_0) was rejected for Q5.

A significant difference was noted for Q8 (“has your skin been bleeding?”) at consult 3 when treatment was compared to placebo:

$P=0.008$

$\alpha = 0.05$

The P-value <0.05 therefore the alternative hypothesis (H_1) was accepted and the null hypothesis (H_0) was rejected for Q8.

There was no significant difference noted for questions 1 and 4.

4.3.2.2 VISUAL SCALE FOR ASSESSMENT OF APPEARANCE OF FEET (VS)

(APPENDIX E) – Kruskal Wallis Test

Table 4.10 Inter-group comparison between the first and final consultation

	Red blotches	Cracked skin	Dry skin	Peeling skin	Bleeding skin	VS (Ave)
Consult 1	.930	.656	2.760	.135	.008*	1.527
Consult 2	.140	.421	1.776	.179	.312	.360

*: Significant values

The inter-group analysis by means of the Kruskal Wallis Test was conducted in order to see if there was a significant difference between the results of the treatment group and the placebo group with regard to the visual scale for assessment of the feet.

At the $\alpha = 0.05$ level of significance, the tests revealed the following:

There was no significant difference noted ($P > 0.05$) for four (Red blotches; Cracked skin; dry skin and Peeling skin) of the five variables (Red blotches; Cracked skin; Dry skin; Peeling skin and Bleeding), therefore the null hypothesis (H_0) was accepted and the alternative hypothesis (H_1) was rejected.

CHAPTER FIVE

DISCUSSION

A statistically significant improvement was demonstrated within the treatment group and placebo group when analysed independently (i.e. intra-group analysis) through the Wilcoxon's Signed Rank Test.

The treatment group showed a significant improvement in three out of the five variables (Red blotches; Cracked skin; Dry skin; Peeling skin and Bleeding skin) tested for visible improvement, and at the end of the trial the P-values were as follows: 0.012 for 'Cracked skin'; 0.004 for 'Dry skin'; and 0.007 for 'Peeling skin'. The P-value for the Total Average Score for Improvement was 0.002 (Table 4.8). The other two variables, namely, 'Red blotches' (0.058) and 'Bleeding skin' (1.000) showed no significant improvement (Table 4.8).

The placebo group showed a significant improvement in only two of the five variables tested for visible improvement. These variables were 'Cracked skin' and 'Peeling skin' with P-values at the end of the trial of 0.025 and 0.008 respectively. The P-value for the Total average Score for Improvement was 0.003 (Table 4.8). The other three variables, namely, 'Red blotches' (0.429); 'Dry skin' (0.054); and 'Bleeding skin' (0.317) showed no significant improvement (Table 4.8).

On comparing the variables for the PPQ (Table 4.1) the treatment group showed significant improvement for all four questions: Q1, Q4, Q5 and Q8 which

pertained to ‘severity of Athlete’s foot’ (Q1); ‘severity of itching’ (Q4); ‘severity of burning sensation’ (Q5) and “severity of bleeding’ (Q8) respectively.

At the end of treatment (consult 3), 67.5% of the treatment group (6 participants) found their “Athlete’s foot” to have changed very much as compared to 20.0% (3 participants) at the 2nd consult (Table 4.2A). Two participants (13.3%) reported their “Athlete’s foot” to have completely gone at day 28 (Table 4.3A).

On comparing the variables for the PPQ (Table 4.1) the placebo group did show significant improvement for all four questions: Q1, Q4, Q5 and Q8 which pertained to ‘severity of Athlete’s foot’ (Q1); ‘severity of itching’ (Q4); ‘severity of burning sensation’ (Q5) and “severity of bleeding’ (Q8) respectively.

At the end of treatment (consult 3), 67.5% (10 participants) found their “Athlete’s foot” to have changed very much as compared to 25.0% (4 participants) at the 2nd consult (Table 4.2B). Three participants reported their “Athlete’s foot” to have completely gone at day 28 (Table 4.3B).

Comparisons between the two groups (Treatment and Placebo) yielded no significant difference (Table 4.4); therefore the treatment complex did not prove to be effective in the treatment of *Tinea pedis*. Possible reasons for this will be discussed in chapter 6.

5.1 DEMOGRAPHICS

There were thirty-one participants in this trial. Seventeen participants were male and fourteen participants were female (Figure 4.1). From this study it can be inferred that males tend to be more affected by the fungi that cause *Tinea*

pedis. It has been considered however that statistically, a larger sample group would be required to re-affirm this statement.

According to Brooks, Butel and Morse (2001), host susceptibility to infection by the fungus is increased by moisture, warmth, specific skin chemistry composition of sebum and perspiration. Non-breathable footwear provides warmth and moisture, creating a favourable condition for the growth of fungi. The male participants in this trial did raise the issue that they spent most of the day in socks and closed shoes due to the fact that this was a work requirement.

5.2 PROBLEMS ENCOUNTERED DURING THIS TRIAL

The problem encountered with this trial was finding a measurement tool that would accurately measure the response to treatment. The choice of measurement was a visual scale (see Appendix E) based on the visual analogue scale (VAS). The VAS is a measurement tool, which takes readings based on human perception. The researcher does however recognize that this is a subjective measurement tool and creates the possibility of bias and human error, which could lead to inaccuracies in measurement. The researcher engaged the assistance of a clinician during the examination and the rating the condition of the feet according to the visual scale. As the consults occurred every 2 weeks, the same clinician was on duty for each patient at his/her consult. The scale (see Appendix E) was also accompanied by pictures (visual aid) representing the degree of severity. Each participant's feet were compared to the pictures of feet affected by "Athlete's foot" ranging from 'mild to severe' and rated accordingly.

Therefore, a certain degree of uniformity and objectivity in the measurement tool was achieved. It must however be mentioned that on certain occasions where the same clinician could not be present due to unforeseen circumstances, a different clinician had to be present. The researcher does therefore recognize that this would have created room for subjectivity as each clinician's opinion of severity would have differed. It was hoped that the visual aids (see Appendix E), in providing a basis for comparison, would minimize the possibility of this problem.

Difonzo *et al* used a 3-point scale (0=none; 1=moderate; 2=severe) for evaluating the clinical symptoms of tinea pedis and tinea manuum namely, erythema, desquamation, vesicles, exudation, maceration and fissuring. Clinical response was supported with mycological testing which consisted of microscopic examination and culture test performed by routine techniques.

Another problem encountered during this trial was patient compliance. Many patients, having had this condition periodically for a number of years, became used to just ignoring the condition. This did create a small problem because the once daily application of the cream seemed to be an effort for some participants. In retrospect, perhaps if these patients had exercised more diligence in the routine application of the cream, the result could have been more positive.

Possible solutions to the above-mentioned problems will be discussed in chapter 6.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

It is concluded that in this placebo controlled study, the topical naturopathic complex, comprising of *Allium sativum* Ø, *Hydrastis canadensis* Ø, *Apis mellifica* D3 and *Urtica urens* D3 (in an aqueous cream base) was in this study, when compared with placebo, found to be ineffective in the treatment of *Tinea pedis*.

6.2 RECOMMENDATIONS

- The referral to complex in all the recommendations below refers to the naturopathic complex used in this study.
- The trial should be conducted using a larger sample group to improve the statistical power of the data analysis.
- A trial comparing the effectiveness of the complex as a treatment as compared to similitum treatment.
- A comparison of the efficacy of the individual remedies comprising the complex in the treatment of *Tinea pedis*.
- A comparison of the efficacy of the individual remedies comprising the complex as compared to the complex.
- A trial evaluating the effectiveness of lifestyle modifications (e.g. breathable footwear) in combination with the complex for treating the symptoms of *Tinea pedis*.
- A study using photography as an objective measurement tool where the

feet are photographed in each consult and the images compared for visible improvement.

- A clinical trial that utilizes microscopy and photography to support clinical evaluation is worth considering for future trials so as to create a more objective measurement system.
- A post trial consultation should be conducted to assess whether the treatment has a lasting curative effect.
- A possible method to ensure patient compliance would be, to provide patients with a mid-week telephonic reminder (about daily application of medication) for each week of the trial period.
- A clinical method of evaluation that can be considered for future trials is the crossover design. This method is used when comparing two treatments for example, comparing Treatment and Placebo. One half of the sample group would receive the Treatment first, followed by Placebo, and the other half would receive Placebo first, followed by Treatment (Maharaj, 2005:63). This method uses participants as their own controls instead of using a separate group. This method of evaluation improves the accuracy of results obtained.

REFERENCES

- Al Hassan, M., Fitzgerald, S.M., Saoudian, M., Krishnaswamy, G., 2004, Dermatology for the practicing allergist: Tinea pedis and its complications, *Clinical And Molecular Allergy*, 2(5), p5-8, p16-20.
- Anders, A. Barnett, R.A., Barone, J., Benneward, P., Berlinsky, G., Bouchez, C., Davis, L.B., Edelson, E., Gilman, R., Hansen, E., Holland, R., Lippert, J., Meyeroff, W., Raymond, N., Taylor, S., Turim, G., Carol, W., 1999, *The Healing Power Of Vitamins, Minerals And Herbs*, Heritage Publishers, South Africa, p62-63, 302-303.
- Arora, D.S., Kaur, J., 1999, Antimicrobial activity of spices. *International Journal of Antimicrobial Agents*, Aug; 12(3): 257-62.
- Beers, M.H. (M.D), Berkow, R. (M.D), 1999, *The Merck Manual of Diagnosis and Therapy*, seventeenth edition, Merck Research Laboratories (Div. of Merck & Co.,Inc), England, p165; p1312.
- Berkow, R. (M.D), 1997, *The Merck Manual of Medical Information*, Home edition, Merck Research Laboratories (Div. of Merck & Co.,Inc), England, p816; p1107.
- Boericke, W., 1998, *Pocket Manual Of Homoeopathic Materia Medica And Repertory*, B.Jain Publishers, New Delhi, p61, p662.
- Brooks, G.F., Butel, J.S., Morse, S.A., 2001, *Jawetz, Melnick and Adelberg's*

Medical Microbiology, 22nd edition, Appleton and Lange, USA, p535-538, p556-560.

Budree, R.S., 2003, *A controlled in vitro study of the effectiveness of the plant tinctures, Commiphora molmol, Hydrastis canadensis and Warburgia salutaris against Candida albicans using the disc diffusion assay*, M.Tech. Homoeopathy mini- dissertation, Durban Institute of Technology, South Africa.

De Schepper, L., 2001, *Hahnemann Revisited: A Textbook of Classical Homoeopathy for the Professional*, Full of Life Publications, USA, p26-27.

De Smidt, W.J., 2001, *An evaluation of the relative Effectiveness of Mother Tincture, 3x and 8x Homeopathic Garlic (Allium sativum) dilutions on Five strains of Nosocomial Multidrug-resistant Micro-organisms in terms of bacteriostatic and bactericidal effects in order to validate the clinical use of garlic in patients infected by these organisms*. M.Tech. Homoeopathy mini-dissertation, Durban Institute of Technology, South Africa.

Digby, B., 1997, *The homoeopathic Family Guide, Classical Homoeopathic Remedies for Common Ailments*, Homoeoforce Division of Pharma Natura, South Africa, p3.

Fitzpatrick, T.B., Johnson, R.A., Polano, M.K., Suurmond, D., Wolff, K., 1992, *Color Atlas and Synopsis of Clinical Dermatology: Common and Serious Diseases*, Mcgraw-Hill Inc., p98-101.

Gaier, H., 1991, *Thorson Encyclopaedic Dictionary of Homoeopathy: The definitive reference to all aspects of homoeopathy*, Harper Collins Publishers, London, p509.

Jacka, J., 1995, *The Complete A to Z of Common Ailments and their Natural Remedies*, W. Foulsham & Co. Limited, Australia, p3-9.

Jouanny, J., Crapanne, J.B., dancer, H., Masson, J.I., 1996 *Homeopathic therapeutics: Possibilities in Acute Pathology*, Editions Bairon, France, p29-31, p67-70, and p208.

Kayne, S.B., 1997, *Homoeopathic Pharmacy: An Introduction and Handbook*, Churchill Livingstone, USA, p25, p50, p127, p106.

Kent, K., 2005, The Effectiveness Of An Oral Homoeopathic Preparation Of Selenium Sulphide 12x In The Management Of Dandruff (Seborrheic Dermatitis Of The Scalp), M. Tech. Homoeopathy mini-dissertation, Durban Institute of Technology, Durban, South Africa.

Mackie, R.M., 1991, *Clinical Dermatology: An illustrated textbook*, 3rd edition, Oxford Medical Publications, USA, p144-145.

Maharaj, S.L, 2005, A Placebo Controlled Study Determining The Effectiveness of a Homoeopathic Complex (Caladium Seguinum 30CH, Nux Vomica 30CH, And Staphysagria Delphinium 30CH) As Compared With Homoeopathic Similimum Treatment In The Management Of Tobacco Addiction, M. Tech. Homoeopathy

mini-dissertation, Durban Institute of Technology, Durban, South Africa.

Marieb, E.N., 2000, *Essentials of Human Anatomy and Physiology*, 6th edition, Addison Wesley Longman Inc., USA, p95-97.

Marieb, E.N., 2003, *Essentials of Human Anatomy and Physiology*, 7th edition, Pearson Education Inc., USA, p100-101.

Murray, M.T., 1995, *The Healing Power Of Herbs: The Enlightened Person's Guide to the Wonders of Medicinal Plants*, 2nd edition, Prima Publishing, USA, P121-129, p162-171.

Naude, D.F., 2001, *The Efficacy of a Topical Homoeopathic Complex (Apis mellifica D3, Aloe vera Ø, Calendula officinalis Ø and Urtica urens Ø) in the Treatment of Sunburn*. M. Tech. Homoeopathy mini-dissertation, Technikon Natal, Durban, South Africa.

Opperman, C., 1997, *The effect of homoeopathic similimum treatment on Atopic Eczema*, M. Tech thesis, Terchnikon Natal, Durban, South Africa.

O'Reilly, W.B., 1996, *Organon of the Medical Art by Dr. Samuel Hahnemann*, 6th edition, p89-94, Aph43-49.

Prescott, L.M., Harley, J.P., Klein, D.A., 1999, *Microbiology*, 4th edition, the McGraw-Hill Companies Inc., USA, p813-814, p692.

Rawat, P.S., 1996, *Select your Dose and Potency*, B. Jain Publishers, New

Delhi, p xxxiv, p xLi-xLii.

Swayne, J., 2000, *International Dictionary of Homeopathy*, Churchill Livingstone. Harcourt Publishers Ltd, UK.

Teleman, S., 2005, The Effectiveness Of Topical Homoeopathic Preparation Of Selenium Sulphide 8x Shampoo In The Management Of Dandruff (Pityriasis Capitis), M. Tech. Homoeopathy mini-dissertation, Durban Institute of Technology, Durban, South Africa.

Tierney, L.M., McPhee, S.J., Papadakis, M.A., 2000, *Current Medical Diagnosis and Treatment*, 39th edition, McGraw-Hill Companies, Inc, USA, p139-142, p1511-1515.

Van Wyk, B.E., Wink, M., 2004, *Medicinal Plants of the World*, First edition, Timber Press, Inc., North America, p434.

Vermeulen, F, 1992, *Synoptic Materia Medica*, 1st edition, Merlijn Publishers, Netherlands, p29-31, p403-405.

Watson, I., 1991, *a Guide to the Methodologies of Homoeopathy*, Miller Turner Printers Ltd, Cumbria, p71-76.

White, G., 1997, *Levene's color atlas of Dermatology*, 2nd edition, Times Mirror International Publishers, London, p154-155.

Yasgur, J., 1992, *A Dictionary of Homeopathic Medical Terminology*, 2nd edition

(revised and enlarged), Van Hoy Publishers, USA, p19.

Yasgur, J., 1997, *Yasgur's Homeopathic Dictionary and Holistic Health reference*, 4th edition, Van Hoy Publishers, U.S.A., p9; p271.

INTERNET REFERENCES:

Al-Wali, N.S., 2004, An alternative treatment for pityriasis versicolor, tinea cruris, tinea corporis, and tinea faciei with topical application of honey, olive oil and beeswax mixture: an open pilot study, *Complementary Therapies in Medicine* [online], 12,45-47. Available on: www.elsevierhealth.com/journals/ctim. [Accessed 16 march 2005].

Bell-Syer, S.E., Hart, R., Crawford, F., Torgerson, D.J., Tyrell, W., Russell, I., 2002, Oral treatments for fungal infections of the skin of the foot, *Evidence Based Nursing* [online], 5(4): 108. Accessed via: PubMed: <http://www.ncbi.nlm.nih.gov/PubMed/> [Accessed 20 nov 2004].

Carroll, R.T. 2002. The placebo effect. The Skeptic's Dictionary [online]. Available: <http://www.skeptic.com/placebo.html>. [Accessed 11 November 2004].

Difonzo, E.M., Papini, M., Cilli, P., Calandra, P. and Panconesi, E., 1995, A double-blind comparison of itraconazole and fluconazole in tinea pedis and tinea manuum, *Journal of the European Academy of Dermatology and Venereology* [online]. 4(2): 148-152. Accessed via: ScienceDirect: <http://www.sciencedirect.com/science> [Accessed 3 march 2005].

Hwang, B.Y., Roberts, S.K., Chadwick, L.R., Wu, C.D., 2003, Antimicrobial constituents from Goldenseal (the Rhizomes of *Hydrastis canadensis*) against Selected oral Pathogens, *Natural Product Chemistry Planta medica* [online], 69:623-627. Accessed via: Pubmed: <http://www.ncbi.nlm.nih.gov/PubMed/>

[Accessed 20 Nov 2004].

Ledzema, E., Marcano, K., Jorquera, A., De Sousa, L., Padilla, M., Pulgar, M., Apitz-Castro, R., 2000, Efficacy of ajoene in the treatment of tinea pedis: a double blind and comparative study with terbanifine, *Journal of the American Academy of Dermatology* [online], 43(5): 829-832. Accessed via: Pubmed: <http://www.ncbi.nlm.nih.gov/PubMed/> [Accessed 26 nov 2004]

Tomlinson, M., 1999, Prescribing complexes: The Highest ideal of cure? [online]. Available on: <http://www.lyghtforce.com/homeopathyonline/issue2/croc.html> [Accessed 11 nov 2004].

APPENDICES

APPENDIX A:

DO YOU SUFFER FROM ATHLETE'S FOOT?

Free treatment is currently being offered at the Homoeopathic Day Clinic.

If you are between the ages of 18 – 60 years and would like to participate, contact Prashadhna Maharaj on the number below to check if you meet the inclusion criteria.

Potential participants may qualify for free treatment.

Prashadhna Devi Maharaj

(032) 551 4649

Cell: 072 779 4396

Thank You

APPENDIX B (ENGLISH):

INFORMATION SHEET FOR THE PARTICIPANT

The efficacy of a topical naturopathic complex (*Allium sativum* Ø; *Hydrastis canadensis* Ø; *Apis mellifica* D3 and *Urtica urens* D3) in the treatment of *Tinea pedis*.

Thank you for volunteering to participate in this study.

I am a 6th year student and in order to obtain my Master's Degree, a mini dissertation needs to be completed.

This study is being conducted to investigate the possibility of a naturopathic alternative to the treatment of *Athlete's Foot*.

The treatment being provided for this study will be free of charge to all participants. There will be two groups of participants in this trial, the treatment group and the placebo group. There is a 50% chance of participants being in a placebo group. Placebo means that the cream will not contain the active ingredients. These participants will be offered free treatment at the end of the study. Participants may benefit from this trial in that they may obtain relief from *Athlete's feet*.

The study will take place at the Homoeopathic Day Clinic located at the Durban Institute Of Technology. The trial will last a period of 28 days. The first consult and the 2nd follow up (final consult) will require about 30 to 40 minutes of your time, during which, your feet will be examined, and you will be required to fill in a set of questionnaires regarding your perception of the treatment. The researcher will be available for questions while you fill in these questionnaires, so that she can assist you with any queries that you may have with regards to the study. The first follow up consult which will take place 2 weeks after the 1st consult will require about 15 to 20 minutes of your time, during which a brief assessment of the progress of the treatment will be made. You will once again be required to complete the questionnaire pertaining to your perception of the treatment up to that point.

All patient information is handled with strict confidence. Only the researcher and research supervisor will have access to patient files. You are free to withdraw from the study at any point without providing reasons for such withdrawal. Once again, thank you for your kind participation in adding to the homoeopathic pool of knowledge.

Prashadhna Devi Maharaj (Researcher).

Tel.: (032) 551 4649 Cell: 072 779 4396

Dr. Corné .M. Hall; B.Sc (PU for CHE); M.Tech. Hom (T.N); (SUPERVISOR) Tel: (031) 2042041

APPENDIX B (ZULU):

INDIKIMBA YENCWADI YENCAZELO

Umpfumela Wokusebenza kwekhamla lokugcoba isikhumba lenaturopathy (okuxubanise I – Allium sativum Ø; Hydrastis canadensis Ø; Apis mellifica D3 ne Urtica urens D3) ekwelapheni impehlo.

Ngiyabonga ukuzinikela kwakho kulolucwaningo.

Ngingumfundi owenza ibanga lesihlanu, ukuze ngithole iziqu zami ze Masters, kumele ngenze lolucwaningo, ngiluphothule kuqala.

Lolucwaningo luhlola ukusebenza kwekhambi lenaturopathy ekwelapheni I – mpehlo.

Imithi yokwelapha ozonikezwa yona imanhala, awuzukuyikhokhela, kubobonke abazozibandakanya kulolucwaningo. Kuzoba namagruphu amabili kulolucwaningo, eyodwa kuzoba eyalabo abathola umuthi wocwaningo abanya abathola lplacebo. Kunamaphesenti angu 50 okuba ube kwi gruphu ye placebo. lplacebo isho ukithi lelikhambi lokugcoba isikhumba alinaso isithako eselaphayo. Labo abathole lplacebo bayobuye bathole imithi yamakhala ekupheleni kocwaningo. Iziguli zingasizakala kulolucwaningo enkingeni yempehlo.

Lolucwaningo luyokwenzelwa ekilini lasemini le Homoeopathy e Durban Institute of Technology. Lolucwaningo luyothatha izinsuku ezingamashumi amabili nesishiyagalombili.

Ukubonwa kwakho kokuqala nokwesibili (okuyoba ngokokugcina) kuyodinga amaminithi angu 30 kuya ku 40, lapho okuyobe kuhlolwa izinyawo zakho, futhi bese ucelwa ukuba ugcwalise uhlu lwemibuzo mayelana nenkinga obhekene nayo yempehlo, nangokulashwa kwayo yilowo muthi owunikeziwe. Umcwaningi uyobe ekhona ngaleso sikhathi kwenzeka lokhu, lokho okuyosiza kakhulu uma unemibuzo mayelna nalolu cwano. Ukubonwa kwakho kwesibili okuyokwenzeka emva kwamaviki amabili emve ni kokuqala kuyo thatha isi khathi esingamaminithi angu 15 kuya ku 20. Ngalesisikhathi kuyokwenziwa ukhlolwa kwakho kwezinyawo nenqubekelaphambili yomuthi. Uyobe futhi usucelwa ukuba ugcwalise uhlu lwemibuzo mayelana nokubona kwakho ngenqubekela phambili yomuthi wokwelapha.

Konke okuyimininingwane yezigulu kuyohlonishwa kakhulu futhi akunakudalulwa. Umcwaningi nomhloli kuphela abayokwazi ngengqikithi yesigulu. Wamukelekile ukuba uzuhoxise kulolucwaningo uma uzwa ukuthi awusenalo uthando nesifiso sokuqhubeka, ngaphandle kokunikeza isizathu.

Ngiyabonga kakhulu ngesikhathi sakho sokuzibandakanya kulolucwaningo nanomthelela nenselelo oyenzayo elwazini lwe Homoeopathy.
Prashadhna Devi Maharaj (Umcwaningi)

Ucingo: (032) 551 4649;

Cell: 072 779 4396

UDokotela Corné. M. Hall; B.Sc (PU for CHE); M. Tech. Hom (T.N); (Umhloli)

Ucingo (031) 204 0241

APPENDIX C1 (ENGLISH):

PATIENT CONSENT FORM

AN INVESTIGATION INTO THE EFFECTIVENESS OF A TOPICAL
NATUROPATHIC COMPLEX IN THE TREATMENT OF ATHLETE'S FOOT

SUPERVISOR: Dr. C.M. Hall; B.Sc (PU for CHE); M.Tech. Hom (T.N)

RESEARCHER: Prashadhna Devi Maharaj; 6th year Homoeopathy student

PLEASE CIRCLE THE APPROPRIATE ANSWER

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

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

I, _____ hereby give consent for the proposed procedure to be performed on me as part of the above mentioned research project.

Signature : _____ Date: _____

Witness: _____ Signature: _____ Date: _____

Research Student: Prashadhna Devi Maharaj

Signature: _____ Date: _____

APPENDIX C1 (ZULU):

IFOMU YOKUGCWALISWA ISIGULI

UCWANINGO NGOKUSETSHENZISWA KWETOPICAL CREAM COMPLEX
EKULAPHENI UCHWANE ATHLETE'S FOOT.

SUPERVISOR/ USEKELA MQONDISI: Dr. C.M. Hall; B.Sc (PU for CHE);
M.Tech. Hom (T.N)

RESEARCHER/UMCWANINGI: Prashadhna Devi Maharaj

KOKOLOZELA IMPENDULO EFANELE.

1. Ulfundile ipheshana elinemininingwane yophenyo? Yebo/Cha
2. Ulitholile ithuba lokubuza imibuzo ngaloluphenyo? Yebo/Cha
3. Ugculisekile yizimpendulo ozitholile? Yebo/Cha
4. Ulitholile ithuba lokubonisana nomcwaningi ngaloluhlelo? Yebo/Cha
5. Ngabe uthole ulwazi olwanele ngalolucwaningo? Yebo/Cha
6. Ngabe unalo uwazi ngemiphumela yokuzibandakanya kulolucwaningo?
Yebo/Cha
7. Ngabe uyazi ukuthi ukhululekile ukuhoxa kulolucwaningo?
Yebo/Cha
 - a) Noma nini noma ngasiphi isikhathi
 - b) Ngaphandle kokunika isizathu ngokuhoxisa
 - c) Ngaphandle kokuthi kuchaphazeleke impilo yakho nekusasa layo
8. Uyavuma ukuzinikela uzibandakanye kulolucwaningo?
Yebo/Cha

Uma uphendule CHA kwenye yemibuzo engenhla; Sicela uthole ulwazi
ngaphambi kokusayina.

Mina, _____
nginka imvume yokuzibandakanya njengengxenywe yalolucwaningo.

Igama likafakazi: _____ Sayina:

Umfundi ongumcwaningi:- Prashadhna Devi Maharaj
Sayina: _____ Usuku _____

APPENDIX C2:

PATIENT DETAILS

AN INVESTIGATION INTO THE EFFECTIVENESS OF A TOPICAL CREAM COMPLEX IN THE TREATMENT OF ATHLETE'S FOOT.

SUPERVISOR: Dr. C.M. Hall; B.Sc (PU for CHE); M.Tech. Hom (T.N)

RESEARCHER: Prashadhna Devi Maharaj; 6th Yr Homoeopathy Student

TO BE COMPLETED BY PARTICIPANT [Please Print]

SURNAME:.....

FULL FIRST NAME:.....

POSTAL ADDRESS:.....

.....

TELEPHONE NO:.....(WORK)

(HOME):.....

CELL NO:.....

SIGNATURE:.....

DATE:.....

APPENDIX D:

PATIENT'S PERCEPTION QUESTIONNAIRE (adapted from C. Opperman; Eczema; 1997; Appendix H)

VISIT NO: -----

NAME: -----

DATE: -----

INSTRUCTIONS:

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

The answers to the following questions ranges from 1 to 5, with 1 being the worst and 5 being the best. For each question mark the number that you think is most applicable to you.

For example

1. How severe would you rate your "Athlete's foot"?
 - 1- Very severe
 - 2- Severe
 - 3- Moderately severe
 - 4- Moderate
 - 5- Mild
-

1.How severe would you rate your "Athlete's foot"? [To be answered in consults 1, 2 & 3]

- 1- Very severe
- 2- Severe
- 3- Moderately severe
- 4- Moderate
- 5- Mild

2. Has your "Athlete's foot" changed at all since treatment? [To be answered in consults 2 & 3]

- 1- Not at all
- 2- Very slightly
- 3- Slightly
- 4- Moderately
- 5- Very much

2.1. If your "Athlete's foot" has changed, how has it changed? [To be answered in consults 2 & 3]

- 1- Getting worse
- 2- Getting slightly better
- 3- Getting better
- 4- Getting much better
- 5- Has completely gone

3. Has the appearance of your feet changed? [To be answered in consults 2 & 3]

- 1- Not at all
- 2- Very slightly
- 3- Slightly
- 4- Moderately
- 5- Very much

4. How do you rate the itching of your skin? [To be answered in consults 1,2 & 3]

- 1- Very severe
- 2- Severe
- 3- Moderately severe
- 4- Slightly
- 5- None

5. How would you rate the burning sensation of your skin? [To be answered in consults 1,2 & 3]

- 1- Very severe
- 2- Severe
- 3- Moderately severe
- 4- Slightly
- 5- None

6. Has the surface texture of your skin changed? [To be answered in consults 2 & 3]

- 1- Become much rougher
- 2- Rougher
- 3- Slightly smoother
- 4- Smoother
- 5- Much smoother

7. Has the peeling of your skin improved? [To be answered in consults 2 & 3]

- 1- Not at all
- 2- Improved slightly
- 3- Improved moderately
- 4- Improved greatly
- 5- No peeling present

8. Has your skin been bleeding? [To be answered in consults 1, 2 & 3]

- 1- Very severe bleeding
- 2- Severe bleeding
- 3- Moderately bleeding
- 4- Slight bleeding
- 5- No bleeding

9. How do you perceive the treatment to be thus far? [To be answered in consults 2 & 3]

- 1- Not good at all
- 2- Fair
- 3- Satisfactory
- 4- Good
- 5- Excellent

APPENDIX E:

VISUAL SCALE FOR THE ASSESSMENT OF APPEARANCE OF FEET (COMPILED BY RESEARCHER)

SUPERVISOR: Dr. C.M. Hall; B.Sc (PU for CHE); M. Tech. Hom (T.N)

RESEARCHER: Prashadhna Devi Maharaj

TO BE COMPLETED BY RESEARCHER AND CLINICIAN

The patient's feet will be examined at the first and last consult by the researcher and the clinician, and will be rated according to the severity of the below-mentioned signs. The answers to the following questions ranges from 1 to 5, with 1 being the worst and 5 being the best.

NAME OF PATIENT: _____

CONSULT: _____

RESEARCHER SIGNATURE: _____

CLINICIAN SIGNATURE: _____

DATE: _____

PLEASE RING THE APPROPRIATE ANSWER

1. Red Blotches

- 1- Very severe
- 2- Severe
- 3- Moderately severe
- 4- Slight
- 5- No red blotches

2. Cracked Skin

- 1- Very severe
- 2- Severe
- 3- Moderately severe
- 4- Slight
- 5- No cracking

3. Dry Skin

- 1- Very severe
- 2- Severe
- 3- Moderately severe
- 4- Slight
- 5- No dryness

4. Peeling Skin

- 1- Very severe
- 2- Severe
- 3- Moderately severe
- 4- Slight
- 5- Absence of peeling

5. Bleeding

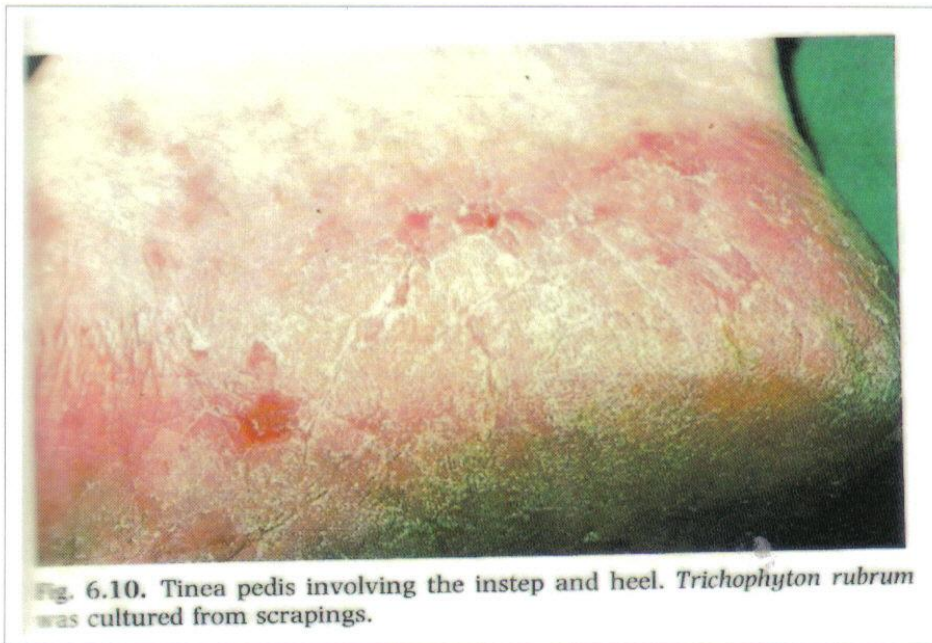
- 1- Very severe
- 2- Severe
- 3- Moderately severe
- 4- Slight
- 5- Absence of bleeding

TINEA PEDIS (“ATHLETE'S FOOT”)

VISUAL SCALE : 1 – 5

(1– VERY SEVERE 5 - NORMAL)

1 – VERY SEVERE



(Mackie, 1993)

2 - SEVERE

3 – MODERATELY SEVERE



52 Tinea pedis Superficial white scales in a moccasin-type distribution. Note arciform pattern of the scales, which is characteristic.

(Fitzpatrick, et.al.1992)

4 - MILD



53 Tinea pedis, interdigital The area is macerated, has opaque white scales and some erosions.

TINEA PEDIS (ATHLETE'S FOOT)

101

(Fitzpatrick, et.al.1992)

APPENDIX F:

A BRIEF CASE HISTORY

NAME:

AGE:

MEDICAL HISTORY:

- Any past or present skin disease?
- Any systemic illnesses e.g. Diabetes, Hypertension etc?
- Are you on any medication?
- Any allergies (including bee stings)?
- Any abnormal reactions to drugs or cosmetics?

FAMILY HISTORY:

TINEA PEDIS (ATHLETE'S FOOT):

- Onset
- Duration
- Signs
- Symptoms
- Treatment sought (Previous/current)

APPENDIX G:

PHYSICAL EXAMINATION

VITAL SIGNS:

Temperature _____ Pulse rate _____
Respiratory rate _____ BP _____
Height _____ Weight _____

GENERAL EXAMINATION:

- Jaundice
- Anaemia
- Cyanosis
- Clubbing
- Dehydration
- Oedema
- Lymphadenopathy

FEET:

- Cracking, peeling and maceration between the toes (particularly between the 3rd, 4th and 5th)
- Moistness between the toes
- Dryness, cracking and peeling on the plantar aspects and sides of the feet
- Bleeding
- Malodour of the feet

APPENDIX H:

LIST OF ANTIFUNGAL DRUGS USED IN THE TREATMENT OF TINEA PEDIS (ATHLETE'S FOOT) AND OTHER FUNGAL INFECTIONS.

1. AZOLES

Azoles are oral antifungal drugs used to treat a wide range of systemic and localized fungal infections. Their mechanism of action is to interfere with the synthesis of lanosterol. Lanosterol is the precursor of cholesterol in mammalian cells and of ergosterol in fungal cells. Azoles are fungi static, which means that they do not kill fungi but inhibit the growth of fungi (Brooks, *et al.* 2000:557).

Clotrimazole:

- Taken orally to prevent and treat oral candidiasis.
- Vaginal tablets are effective for vaginal candidiasis.
- Available as topical preparation for cutaneous fungal infections.
- It is highly toxic and therefore cannot be used systemically (Tierney, *et al.* 2000:1512).

Miconazole:

- It has substantial toxicity and little clinical activity.
- It is used as a 2% cream for superficial fungal infections.
- Used in vaginal candidiasis (Tierney, *et al.* 2000:1512)

Ketoconazole:

- Given orally as a single daily dose with food.
- Used in the treatment of mucocutaneous candidiasis and superficial fungal infections.
- Ketoconazole is the most toxic azole.
- Therapeutic doses may inhibit the synthesis of testosterone and cortisol. This may cause a variety of reversible side effects such as gynecomastia in males, decreased libido, menstrual irregularities and occasionally adrenal insufficiency (Brooks, *et al.* 2000:558-559).
- Other adverse side effects include nausea, vomiting, skin rashes and occasional elevations in liver enzymes. On rare occasions symptomatic and fatal hepatitis can occur (Tierney, *et al.*2000: 1514).

Fluconazole:

- Is a water-soluble drug and can be administered orally and intravenously.
- Utilized in the treatment of candidiasis in the immuno suppressed.
- *Candida albicans* is usually sensitive to Flucoazole, but other strains are resistant.
- Fluconazole does not cause side effects at therapeutic doses but can cause asymptomatic elevation in liver enzymes and in rare cases hepatitis.
- It is an expensive drug (Tierney, *et al.* 2000:1514-1515).

2.GRISEOFULVIN

- It inhibits the growth of fungi that cause superficial skin infections.
- It is an orally administered drug that is deposited in the skin, hair and nails.
- Griseofulvin binds to keratin and makes it resistant to fungal growth.
- Treatment is administered for 305 weeks if only the skin is involved, and 3 to 6 months and longer if the hair and nails are involved.
- Side effects include headache, nausea, vomiting, diarrhoea, photosensitivity and leukopenia (Tierney, *et al.* 2000:1512).

3.NYSTATIN

- Nystatin has a wide spectrum of antifungal activity but is used almost exclusively to treat superficial fungal infections (Tierney, *et al.* 2000:1513).
- It is available in oral suspension and ointments, gels and creams and is used topically.
- It is not absorbed from the mucous membranes or gastrointestinal tract.
- It cannot be systemically administered because of its high toxicity (Tierney, *et al.* 2000:1513).

4.TERBANIFINE

- Terbanifine is an allylamine drug, meaning that it blocks ergosterol synthesis and inhibits fungal cell membrane function.
- It is effective in treating nail infections.
- The common side effects include gastrointestinal upset, headaches, skin reactions, and loss of the sense of taste (Brooks, *et al.* 2000:559).