The efficacy of a homoeopathic complex (*Kalium bromatum* 9CH, *Natrum muriaticum* 9CH, *Selenium* 9CH, *Sulphur* 9CH and *Thuja occidentalis* 9CH) in the treatment of acne vulgaris

By

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Mini-dissertation submitted in partial compliance with the requirements of the Master's Degree in Technology: Homoeopathy

In the Faculty of Health Sciences

Durban University of Technology

Durban

June 2013

This study represents original work by the author and has not been submitted in any form to another University. Where use was made of the work of others, it has been duly acknowledged in the text.

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

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Approved for final submission

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DEDICATION

I would like to dedicate this mini-dissertation to:

My late mother: For being so loving, caring and supportive during the course of the research, clinical trial and write-up of this mini-dissertation. For being a kind, generous, loving and understanding mother. Indeed, my mother was a wonderful person and a special human being.

My father: Thank you for being so loving, caring and supportive during the course of the research.

My late grandfather: For always encouraging me and being a real inspiration to me.

My grandmother: Thank you for being so supportive and encouraging during the research process.

My wife: Thank you for being so loving, caring, supportive and patient with me during the research process.

My beautiful children: Thank you for being such adorable, delightful and lovely children.

AKNOWLEDGEMENTS

I would like to thank:

Allah (Almighty God): For keeping me calm, guiding me and helping me overcome all obstacles during this research, and enabling me to complete this research and mini-dissertation.

Dr Richard Steele (my supervisor): Thank you for being such a brilliant supervisor. Thank you for your dedication, hard work, assistance and guidance through the research process.

My family: Thank you for your emotional and financial support. Thank you for being loving, caring, understanding and supportive during this research.

Tonya Esterhuizen (my statistician): Thank you for your assistance and guidance through the statistical analysis of this research.

My lecturers: I would like to thank all of my lecturers from the homoeopathy, chiropractic, basic medical sciences, physics and chemistry departments. Thank you all for being such wonderful lecturers and providing me with invaluable knowledge during my period of study.

My patients: I would like to thank all of the patients that participated in this clinical trial. Thank you all for being so kind and co-operative during the clinical trial.

ABSTRACT

Introduction

Acne vulgaris is a common skin condition (disorder of the pilosebaceous duct) which is universal in adolescence. Acne vulgaris can persist into adulthood, with 1% of males and 5% of females requiring treatment until 40 years of age.

Aim

The aim of this study was to determine the efficacy of a homoeopathic complex (*Kalium bromatum* 9CH, *Natrum muriaticum* 9CH, *Selenium* 9CH, *Sulphur* 9CH and *Thuja occidentalis* 9CH), compared to placebo, in the treatment of acne vulgaris.

Methodology

A total of 37 participants between the ages of 18 and 31 were recruited from the Greater Durban area by means of poster advertisements placed on notice boards in shops, pharmacies, health shops, hospitals, schools, tertiary institutions including Durban University of Technology, and other public areas. Handouts were also left at these areas for people to take home. The final sample consisted of 34 participants due to the drop out of 3 participants. After participants read an information letter (English or Zulu), fulfilled the inclusion and exclusion criteria of the research, were diagnosed as having acne vulgaris by the researcher and completed an informed consent form (English or Zulu) and confidential patient information form (English or Zulu), they were randomly assigned to an experimental (homoeopathic complex) group and a control (placebo) group. In the final sample, the experimental (homoeopathic complex) group consisted of 7 males and 10 females, and the control (placebo) group consisted of 9 males and 8 females. Consultations took place at the Durban University of Technology Homoeopathic Day Clinic, and consisted of 3 consultations, an initial consultation followed by 2 follow-up consultations at 3 weekly intervals. The treatment period for each participant was therefore 6 weeks.

A case history was taken and a complete physical examination was performed for all participants. The Leeds counting technique was used to assess and measure the response to treatment. The lesions assessed were the non-inflamed lesions (blackheads and whiteheads), inflamed lesions (papules, pustules, nodules, cysts and deep pustules) and the total number of acne lesions (number of non-inflamed and inflamed lesions combined). The response to treatment was measured in terms of a reduction in the number of non-inflamed, number of inflamed and total number of acne lesions, on the face, over the 6 weeks.

SPSS version 20 was used to analyse the data. A p value of < 0.05 was considered as statistically significant. Non-parametric tests were used to analyse the data. The number of non-inflamed, number of inflamed and total number of acne lesions were compared within groups using the Friedman test and between groups using the Mann-Whitney U test. The number of lesions was compared separately for males and females, and also without gender classification.

Results

In females, the control (placebo) group showed a statistically significant reduction in the total number of acne lesions when compared to the experimental group ($p = 0.034$). However, as a whole, it was concluded from the results of this study that there was no significant difference in the number of non-inflamed ($p = 0.193$), number of inflamed ($p = 0.290$), and total number of acne lesions ($p = 0.193$) between the experimental (homoeopathic complex) and control (placebo) groups. Both groups showed a similar reduction when compared to each other.

Conclusion

It was concluded that the homoeopathic complex was not effective in the treatment of acne vulgaris.

TABLE OF CONTENTS

DEDICATION i

AKNOWLEDGEMENTS ii

ABSTRACT iii

TABLE OF CONTENTS v

LIST OF TABLES xii

LIST OF FIGURES xiv

LIST OF APPENDICES xv

DEFINITION OF TERMS xvi

CHAPTER 1 1

INTRODUCTION 1

1.1 CONTEXT OF THE RESEARCH 3

1.2 PROBLEM STATEMENT 4

1.3 AIM OF THE STUDY 5

1.4 OBJECTIVE OF THE STUDY 5

1.5 HYPOTHESIS 5

CHAPTER 2 6

REVIEW OF THE RELATED LITERATURE 6

2.1 DEFINITION AND CLASSIFICATION 6

2.2 EPIDEMIOLOGY AND INCIDENCE 6

2.3 PATHOGENESIS 6

2.4 SIGNS AND SYMPTOMS OF ACNE VULGARIS 8

2.5 CLINICAL VARIANTS OF ACNE 9

2.6 DIAGNOSIS 9

2.7 AETIOLOGY AND RELATED FACTORS 10

2.7.1 Androgens and sebum production 10
2.7.2 Genetics 11
2.7.3 Diet 11
2.7.4 Psychological effects of acne vulgaris 13
2.7.5 Relationship between acne vulgaris, psychological effects and nutritional factors 14
2.7.6 Smoking and acne vulgaris 15
2.7.7 Myths and misconceptions 16
2.8 ALLOPATHIC TREATMENT 16
2.8.1 Acne preparations for topical use 17
2.8.1.1 Precipitated sulphur 17
2.8.1.2 Benzoyl peroxide 17
2.8.1.3 Azelaic acid 17
2.8.1.4 Abrasive agents 18
2.8.1.5 Degreasing agents 18
2.8.1.6 Anti-infectives for acne treatment 18
2.8.1.7 Topical retinoids 18
2.8.2 Acne preparations for systemic use 19
2.8.2.1 Isotretinoin 19
2.8.2.2 Oral antibiotics 20
2.8.2.3 Oral contraceptives 21
2.8.3 Other treatment considerations 21
2.9 NATUROPATHIC DIET APPROACH FOR ACNE TREATMENT 23
2.10 HERBAL TREATMENT 24
2.11 HOMOEOPATHIC TREATMENT AND RESEARCH 26
2.11.1 Homoeopathic treatment in general 27
2.11.2 The potency scale 29

2.11.2.1 The decimal scale 29
2.11.2.2 The centesimal scale 29
2.11.2.3 The fifty millesimal scale 29
2.11.2.4 Methods of potentisation 30
2.11.2.4.1 Trituration 30
2.11.2.4.2 Succussion 30
2.11.3 Safety of homoeopathic medicines 30
2.11.4 Homoeopathic research 32
2.11.5 The homoeopathic complex utilised in this study 34
2.12 ACNE VULGARIS AND PATIENT EDUCATION 35
2.13 THE LEEDS COUNTING TECHNIQUE 36
CHAPTER 3 38
MATERIALS AND METHODS 38
3.1 POPULATION, SAMPLE, PATIENT RECRUITMENT AND SELECTION 38
3.1.1 Inclusion criteria 42
3.1.2 Exclusion criteria 43
3.2 ETHICS 43
3.3 EVALUATION OF THE RESPONSE TO TREATMENT 44
3.3.1 Measurement tool 44
3.3.2 Counting of acne lesions 45
3.3.3 Pitfalls for the unwary 46
3.4 PREPARATION OF THE HOMOEOPATHIC COMPLEX AND PLACEBO 47
3.5 DISPENSING AND ADMINISTRATION OF THE MEDICINE 48
3.6 SAFETY OF HOMOEOPATHIC MEDICINE 49
3.7 CONSULTATIONS 50
3.7.1 The first consultation 50

3.7.2 The second consultation 51
3.7.3 The third consultation 51
3.8 DATA COLLECTION AND STATISTICS 53
3.8.1 Data collection 53
3.8.2 Statistical analysis 53
3.8.2.1 The Friedman Test 53
3.8.2.2 The Mann-Whitney U Test 54
3.8.2.3 Procedures 55
3.8.2.3.1 Procedure 1 (intra-group analysis) 55
3.8.2.3.2 Procedure 2 (inter-group analysis) 55
CHAPTER 4 56
RESULTS 56
4.1 INTRODUCTION 56
4.2 DEMOGRAPHICS 57
4.2.1 Age 57
4.2.2 Race 58
4.2.3 Gender 58
4.3 PROCEDURE 1 (INTRA-GROUP ANALYSIS) 59
4.3.1 Statistical analysis involving gender classification 59
4.3.1.1 Non-inflamed lesions 59
4.3.1.1.1 Males: complex group 59
4.3.1.1.2 Males: placebo group 60
4.3.1.1.3 Females: complex group 60
4.3.1.1.4 Females: placebo group 61
4.3.1.2 Inflamed lesions 62
4.3.1.2.1 Males: complex group 62

4.3.1.2.2 Males: placebo group 62
4.3.1.2.3 Females: complex group 63
4.3.1.2.4 Females: placebo group 64
4.3.1.3 Total acne lesions 64
4.3.1.3.1 Males: complex group 65
4.3.1.3.2 Males: placebo group 65
4.3.1.3.3 Females: complex group 66
4.3.1.3.4 Females: placebo group 66
4.3.2 Statistical analysis without gender classification 67
4.3.2.1 Non-inflamed lesions 67
4.3.2.2 Inflamed lesions 68
4.3.2.3 Total acne lesions 69
4.4 PROCEDURE 2 (INTER-GROUP ANALYSIS) 70
4.4.1 Statistical analysis involving gender classification 70
4.4.1.1 Non-inflamed lesions 70
4.4.1.1.1 Males 70
4.4.1.1.2 Females 71
4.4.1.2 Inflamed lesions 73
4.4.1.2.1 Males 73
4.4.1.2.2 Females 74
4.4.1.3 Total acne lesions 76
4.4.1.3.1 Males 76
4.4.1.3.2 Females 77
4.4.2 Statistical analysis without gender classification 80
4.4.2.1 Non-inflamed, inflamed and total acne lesions 80
4.5 SUMMARY AND CONCLUSION 84

4.5.1 Non-inflamed lesions 84
4.5.2 Inflamed lesions 84
4.5.3 Total acne lesions 85
CHAPTER 5 86
DISCUSSION 86
5.1 DISCUSSION OF STATISTICAL ANALYSIS AND RESULTS INVOLVING GENDER CLASSIFICATION 86
5.1.1 Non-inflamed lesions 86
5.1.2 Inflamed lesions 87
5.1.3 Total acne lesions 87
5.2 DISCUSSION OF STATISTICAL ANALYSIS AND RESULTS WITHOUT GENDER CLASSIFICATION 88
5.3 DISCUSSION OF THE PLACEBO EFFECT 88
5.4 FACTORS THAT COULD HAVE POSSIBLY AFFECTED THE OUTCOME OF THE STUDY 90
5.4.1 Stress 90
5.4.2 Compliance with treatment 91
5.4.3 Counting of lesions 91
5.4.4 Diet 91
5.4.5 Weather 92
5.4.6 Premenstrual factors 92
5.5 RELATIONSHIP TO OTHER ACNE STUDIES 93
5.6 SIGNIFICANCE OF THE FINDINGS OF THE STUDY 95
CHAPTER 6 97
CONCLUSION AND RECOMMENDATIONS 97
6.1 RECOMMENDATIONS 97
LIST OF REFERENCES 99

APPENDICES.. 113

LIST OF TABLES

Table 1: Age distribution within the experimental (complex) and control (placebo) groups. 57

Table 2: Race distribution within the experimental (complex) and control (placebo) groups. 58

Table 3: Gender distribution within the experimental (complex) and control (placebo) groups. 58

Table 4: Rate of change in the number of non-inflamed lesions between consultations for males in the experimental (complex) group. 59

Table 5: Rate of change in the number of non-inflamed lesions between consultations for males in the control (placebo) group. 60

Table 6: Rate of change in the number of non-inflamed lesions between consultations for females in the experimental (complex) group. 60

Table 7: Rate of change in the number of non-inflamed lesions between consultations for females in the control (placebo) group. 61

Table 8: Rate of change in the number of inflamed lesions between consultations for males in the experimental (complex) group. 62

Table 9: Rate of change in the number of inflamed lesions between consultations for males in the control (placebo) group. 62

Table 10: Rate of change in the number of inflamed lesions between consultations for females in the experimental (complex) group. 63

Table 11: Rate of change in the number of inflamed lesions between consultations for females in the control (placebo) group. 64

Table 12: Rate of change in the total number of acne lesions between consultations for males in the experimental (complex) group. 65

Table 13: Rate of change in the total number of acne lesions between consultations for males in the control (placebo) group. 65

Table 14: Rate of change in the total number of acne lesions between consultations for females in the experimental (complex) group. 66

Table 15: Rate of change in the total number of acne lesions between consultations for females in the control (placebo) group. 66

Table 16: Rate of change in the number of non-inflamed lesions between consultations within the experimental (complex) group and within the control (placebo) group. 67

Table 17: Rate of change in the number of inflamed lesions between consultations within the experimental (complex) group and within the control (placebo) group. 68

Table 18: Rate of change in the total number of acne lesions between consultations within the experimental (complex) group and within the control (placebo) group. 69

Table 19: Change in the number of non-inflamed lesions between experimental (complex) and control (placebo) groups in males. 70

Table 20: Hypothesis test summary. The p value for inter-group comparison of the number of non-inflamed lesions in males. 70

Table 21: Change in the number of non-inflamed lesions between experimental (complex) and control (placebo) group in females. 71

Table 22: Hypothesis test summary. The p value for the inter-group comparison of the number of non-inflamed lesions in females. 72

Table 23: Change in the number of inflamed lesions between the experimental (complex) and control (placebo) group in males. 73

Table 24: Hypothesis test summary. The p value for the inter-group comparison of the number of inflamed lesions in males. 73

Table 25: Change in the number of inflamed lesions between the experimental (complex) and control (placebo) group in females. 74

Table 26: Hypothesis test summary. The p value for the inter-group comparison of the number of inflamed lesions in females. 75

Table 27: Change in the total number of acne lesions between the experimental (complex) and control (placebo) group in males. 76

Table 28: Hypothesis test summary. The p value for the inter-group comparison of the total number of acne lesions in males. 76

Table 29: Change in the total number of acne lesions between the experimental (complex) and control (placebo) group in females. 77

Table 30: Hypothesis test summary. The p value for the inter-group comparison of the total number of acne lesions in females. 78

Table 31: Change in the number of non-inflamed, number of inflamed and total number of acne lesions between the experimental (complex) and control (placebo) groups. 80

Table 32: Hypothesis test summary. The p value for inter-group comparisons of the number of non-inflamed, number of inflamed and total number of acne lesions. 81

LIST OF FIGURES

Figure 1 cross section of normal skin and skin with acne (Knot, 2012)..... 7

Figure 2: Equivalence of the rate of change in the median number of non-inflamed lesions in males in the experimental (complex) and control (placebo) groups over time. 71

Figure 3: Equivalence of the rate of change in the median number of non-inflamed lesions in females in the experimental (complex) and control (placebo) groups over time 72

Figure 4: Equivalence of the rate of change in the median number of inflamed lesions in males in the experimental (complex) and control (placebo) groups over time. 74

Figure 5: Equivalence of the rate of change in the median number of inflamed lesions in females in the experimental (complex) and control (placebo) groups over time. 75

Figure 6: Equivalence of the rate of change in the median total number of acne lesions in males in the experimental (complex) and control (placebo) groups over time. 77

Figure 7: Equivalence of the rate of change in the median total number of acne lesions in females in the experimental (complex) and control (placebo) groups over time. 79

Figure 8: Equivalence of the rate of change in the median number of non-inflamed lesions in the experimental (complex) and control (placebo) groups over time. 82

Figure 9: Equivalence of the rate of change in the median number of inflamed lesions in the experimental (complex) and control (placebo) groups over time… 83

Figure 10: Equivalence of the rate of change in the median total number of acne lesions in the experimental (complex) and control (placebo) groups over time… 84

LIST OF APPENDICES

APPENDIX A: Poster advertisements and handouts 113
APPENDIX B1: Information letter in English 114
APPENDIX B2: Information letter in Zulu 118
APPENDIX C1: Informed consent form in English 121
APPENDIX C2: Informed consent form in Zulu 123
APPENDIX D1: Child assent form in English 125
APPENDIX D2: Child assent form in Zulu 128
APPENDIX E1: Confidential patient information form in English 131
APPENDIX E2: Confidential patient information form in Zulu 133
APPENDIX F: Case history 135
APPENDIX G: Physical examination 138
APPENDIX H: Assessment sheet (The Leeds counting technique) 142
APPENDIX I1: How to take homoeopathic medication instructions in English 143
APPENDIX I2: How to take homoeopathic medication instructions in Zulu 144
APPENDIX J: Raw data 145

DEFINITION OF TERMS

Acne vulgaris: The formation of comedones, papules, pustules, nodules, and/or cysts as a result of obstruction and inflammation of pilosebaceous units (hair follicles and their accompanying sebaceous gland) (Beers, Porter, Jones, Kaplan and Berkwits, 2006:941).

Allopathy: A therapeutic system in which a disease is treated by producing a second condition that is incompatible with or antagonistic to the first (Stedman, 2005:50).

Antiseptic: An antiseptic is a chemical compound that retards the growth of micro-organisms without destroying them (Nzimande, 2005:2).

Potentisation (drug dynamisation): The process in which a crude medicinal substance is reduced to its sub-physiological state, and its latent medicinal properties are unfolded, by the method of potentisation or dynamisation (Chauhan and Gupta, 2007:11).

Homoeopathy: A system of medicine which treats diseases by remedies prescribed in minute doses, which if given to a healthy person would develop symptoms like those of the disease (Chauhan and Gupta, 2007:11).

Homoeopathic aggravation: A worsening of symptoms occurring close to the time of taking the remedy and is either followed by the symptoms settling again to their previous state or by an overall improvement of symptoms (Thompson, Barron and Spence, 2004:204).

Infection: Invasion of the body by pathogenic micro-organisms causing diseases (Nzimande, 2005:4).

Law of minimum dose: The minimum dose is that quantity of medicine which is capable of bringing about the curative action (Chauhan and Gupta, 2007:11).

Law of similia: The symptoms experienced by the sick are not the disease, but are a reaction of the defence mechanism of the body which mobilizes its resources to counteract the morbific influence. The drug must have the capacity to produce, in a healthy person, similar symptoms of the disease being manifested by the sick person (Chauhan and Gupta, 2007:11).

Materia medica: A pharmacological text; a reference book containing lists of medicines and their uses (O'Reilly, 1996:325).

Placebo: A pharmacologically inert substance, having no physiological action (Chauhan and Gupta, 2007:53).

Potency: Potency is the unit of drug strength (Chauhan and Gupta, 2007:50).

Signs: These are detected by the observer, for example, abdominal enlargement or dullness on percussion. Objective symptoms are usually spoken of as signs (Chauhan and Gupta, 2007:33).

Simillimum: The medicinal substance capable of producing a set of symptoms which are the most similar to those in the case of the disease to be cured (O'Reilly, 1996:350).

Similia similibus curentur: Let similars be cured by similars. *Similia similibus curentur* is the law of similars upon which the homoeopathic medical art is based (O'Reilly, 1996:349).

Succussion: Vigorous shaking with impact. Part of a multi-step process for potentising substances to bring out their medicinal powers (O'Reilly, 1996:353).

Suppression: The inhibition of the natural expression by some unnatural method, which is against the normal natural course (Chauhan and Gupta, 2007:15).

Theory of vital force: This theory proposes that the life energy, which is also called the "vital force" animates our body. Without this energy the material organism is capable of no sensation, function or self-preservation. All the functions of life are carried out by this immaterial being. It animates the material organism in health and in disease (Chauhan and Gupta, 2007:12).

Totality of symptoms: All the signs and symptoms of a disease (either a natural one or an artificial medicinal one); the entire, outwardly reflected picture of a disease (O'Reilly, 1996:358).

Trituration: The act of rubbing, grinding, or pounding into fine particles or a powder. A dry method of potentising medicinal substances whereby the substance is finely ground in a mortar with a certain proportion of milk sugar, thereby progressively attenuating it. The potentisation of medicinal substances is also accomplished by means of dilution and succussion, which Hahnemann describes as a kind of trituration (O'Reilly, 1996:358).

CHAPTER 1
INTRODUCTION

Acne vulgaris is defined as a chronic disorder of the pilosebaceous duct with increased sebum production, ductal hypercornification, a deranged symbiotic relationship with commensal microorganisms (*Propionibacterium acnes)* and cutaneous inflammation. Acne vulgaris is a disorder that is universal in adolescence. However, 1% of males and 5% of females may need treatment up until 40 years of age (Davey, 2010:440). Therefore, although acne begins frequently during adolescence, it may occur well into adult life (Gibbon, 2005:191). Cordain, Lindeberg, Hurtado, Hill, Eaton, and Brand-Miller (2002:1584) state that acne affects a significant amount of adults over the age of 25 years.

The fundamental abnormality is probably an increased production of sebum. The sebaceous glands are driven by the hormone androgen. Seborrhoea, comedones, papules, pustules, nodules, cysts and scars are clinical features of acne vulgaris. These lesions are distributed on the face, neck, back and chest (Davey, 2010:440). Investigations are rarely required (Schofield and Rees, 2006:1300). Only if Cushing's syndrome or virilisation is suspected, will investigations be required (Davey, 2010:440).

According to Morrison (1998), the main homoeopathic remedies for acne include *Calcarea silicata*, *Calcarea sulphurica*, *Hepar sulphuris*, *Kalium bromatum*, *Lachesis mutis*, *Mercurius*, *Silica*, *Sulphur* and *Thuja occidentalis*. The majority of patients who come for homoeopathic treatment are already on some form of allopathic treatment (Morrison, 1998). For instance, Biswas, Mondal, Saha, Dutta, and Lahiri (2010:40) found that 82.7% of patients received allopathic treatment and 17.3% had received either homoeopathic or ayurvedic or combined homoeopathic and ayurvedic treatment before attending the Acne Clinic at Institute of Post Graduate Medical Education and Research (IPGME&R) and SSKM Hospital, Kolkata, India. Homoeopathic treatment is non-toxic (Jouanny,

Crapanne, Dancer and Masson, 1994:274) and homoeopathic medicines are regarded as very safe because of the high dilutions used (Thompson, Barron and Spence, 2004:203).

Allopathic treatment includes topical antibiotics, keratolytics and retinoids (for mild acne), both topical and systemic therapy (for moderate to severe acne), oral antibiotics, and anti-androgenic hormones (i.e. for women, an appropriate contraceptive pill). Severe nodulocystic acne or a failure to respond to other treatments is an indication for isotretinoin. This drug is highly effective and affects all four aetiological factors in acne vulgaris. It reduces the production of sebum by 75-90% (Davey, 2010:440). However, isotretinoin has many side effects such as drying of the skin and mucous membranes, and is highly teratogenic (Schofield and Rees, 2006:1300).

In summary, acne vulgaris is a skin disease that is chronic and can persist into adulthood. Acne can cause significant psychological morbidity. Immune mediated inflammatory changes precede follicular hyperkeratinisation and *Propionibacterium acnes* colonisation. Acne can be significantly cleared by oral isotretinoin but the use of isotretinoin is limited by teratogenicity and other side-effects (Williams, Dellavalle and Garner, 2012:369).

Treatment failure can be caused by non-compliance. In clinical practice, topical regimens usually have the worst adherence rates. Factors that are associated with decreased adherence are male gender, frequency of dosing, consumption of alcohol and smoking. Factors that are associated with increased adherence are satisfaction with physician and a high level of embarrassment associated with acne. Compliance is a key strategy in treatment response and must be encouraged with simplification of medication regimes, positive reinforcement of patient behaviour and written education (Nguyen and Su, 2011:125).

This double-blind placebo controlled clinical trial aimed to determine the efficacy of a homoeopathic complex (*Kalium bromatum* 9CH*, Natrum muriaticum* 9CH*, Selenium* 9CH*, Sulphur* 9CH and *Thuja occidentalis* 9CH) in the treatment of

acne vulgaris, compared to a placebo. Convenience sampling was used to recruit 34 participants from the Greater Durban area. Consultations took place at the Durban University of Technology Homoeopathic Day Clinic and consisted of 3 consultations over a period of 6 weeks for each participant.

The assessment tool was the Leeds counting technique for assessing acne vulgaris (Burke and Cunliffe, 1984:87-92). The data was analysed statistically using SPSS version 20 (IBM Corp, 2011).

1.1 CONTEXT OF THE RESEARCH

Acne vulgaris affects 79% to 95% of the adolescent population in westernised societies. Acne also affects a significant amount of adults over the age of 25 years (Cordain et al., 2002:1584). Therefore, acne can occur well into adult life (Gibbon, 2005:191).

Acne has a huge impact on the well-being and quality of life of acne sufferers. Research indicates that almost half of acne sufferers (48%) state that their daily lives are affected by this condition. Adolescents who lack personal experience of acne perceive acne very negatively (Pawin, Chivot, Beylot, Faure, Poli, Revuz and Drèno, 2007:310, 313).

The main allopathic treatment, isotretinoin, has many adverse effects, according to the South African Medicines Formulary (Gibbon, 2005:194). Isotretinoin (brand name: Roaccutane®) commonly causes drying of the skin and mucous membranes. In addition, isotretinoin is highly teratogenic (Schofield and Rees, 2006:1300). In a population-based analysis of laboratory abnormalities during isotretinoin therapy for acne vulgaris conducted by Zane, Leyden, Marqueling and Manos (2006:1019), 44% of patients showed a value over the normal range for serum triglyceride levels. Side effects of isotretinoin also include depression and suicide (Schofield and Rees, 2006:1300).

Alternative treatment of acne vulgaris, e.g. homoeopathy, needs to be explored due to many reasons. According to De Schepper (2005:3, 455), allopathic medicine is “an unsatisfying experience for patient and practitioner alike”, and numerous allopathic medications cause side effects that are painful or harmful. In addition, allopathy can be very expensive (De Schepper, 2005:3), as confirmed by Magin, Pond, Smith and Watson (2005:68) who conclude that acne medicated washes can be very costly. There is also the issue of side effects of allopathic drugs, as outlined above in respect of isotretinoin.

According to Smolle (2003:96), at the present stage of knowledge there is no sound evidence for homoeopathy in the treatment of skin diseases which would justify its wide application. The author points out that only a few controlled trials have been conducted in homoeopathy, most of which have negative results. Those trials with positive results have not been reproduced.

Bekker (2004) conducted a clinical trial of a homoeopathic complex called Testis Compositum® and found that it had a significant effect in terms of improving acne vulgaris. The positive findings of this study warrants further investigation of homoeopathic interventions in this field.

Due to the above information it is appropriate that alternative therapies, such as homoeopathy, be carefully researched and be made available to the public. Homoeopathy does not produce any side effects and aims to increase the quality of life as it heals (De Schepper, 2005:455).

1.2 PROBLEM STATEMENT

Acne vulgaris is an almost universal skin disease that affects 79% to 95% of adolescents in westernised societies as well as a significant amount of adults over the age of 25 years (Cordain et al., 2002:1584). One percent of men and 5% of women may require treatment up until 40 years of age (Davey, 2010:440). Acne begins frequently during adolescence, but can occur well into adult life (Gibbon, 2005:191).

Isotretinoin, indicated primarily to manage intractable acne, has various side effects such as drying of the mucosa (e.g. dry mouth, nose and eyes, cheilitis, keratitis, stomatitis and epistaxis), skin rashes, increased intracranial pressure (causing headache and visual disturbances), musculoskeletal pain, depression, behavioural disorders, etc. (Gibbon, 2005:194). Acne can cause significant psychological morbidity (Williams, Dellavalle and Garner, 2012:369).

Acne vulgaris presents a significant financial burden to the community and the psychosocial impact of acne can be severe, life-altering and life-threatening (Nguyen and Su, 2011:119).

1.3 AIM OF THE STUDY

The aim of this study was to determine the efficacy of a homoeopathic complex (*Kalium bromatum* 9CH, *Natrum muriaticum* 9CH, *Selenium* 9CH, *Sulphur* 9CH and *Thuja occidentalis* 9CH), compared to a placebo, in the treatment of acne vulgaris, by using the Leeds counting technique for assessing acne vulgaris (Burke and Cunliffe, 1984:87-92).

1.4 OBJECTIVE OF THE STUDY

The objective of this study was to evaluate the effectiveness of a homoeopathic complex, by measuring the response of the patients' acne vulgaris (acne lesions), on the face, to the homoeopathic complex, in terms of a reduction in the number of non-inflamed, number of inflamed and total number of acne lesions.

1.5 HYPOTHESIS

Null hypothesis: The homoeopathic complex is not effective in the treatment of acne vulgaris.

Alternative hypothesis: The homoeopathic complex is effective in the treatment of acne vulgaris.

CHAPTER 2

REVIEW OF THE RELATED LITERATURE

2.1 DEFINITION AND CLASSIFICATION

Acne vulgaris is the formation of comedones, papules, pustules, nodules, and/or cysts as a result of obstruction and inflammation of pilosebaceous units (hair follicles and their accompanying sebaceous gland) (Beers et al., 2006:941). Classification is according to whether it is mild (mainly comedones), moderate (comedones, papules and pustules), severe (numerous papules and pustules, and occasional nodular inflamed lesions) and very severe (nodulocystic acne and acne conglobata) (BMJ Evidence Centre, 2010).

2.2 EPIDEMIOLOGY AND INCIDENCE

Adolescents are most often affected by acne vulgaris (Beers et al., 2006:941). Acne vulgaris commonly begins in adolescence and resolves spontaneously in adulthood (Ghodsi, Orawa and Zouboulis, 2009:2136). However, acne remains common throughout the adult years. In all age groups 20 years and above, acne affects women more than men. Acne reported in teenagers was not significantly different between males and females (68.5% males and 66.8% females) (Collier, Harper, Cantrell, Wang, Foster and Elewski, 2008:58, 56).

Acne vulgaris affects 79% to 95% of the adolescent population in westernised societies (Cordain et al., 2002:1584). During the teenage years acne is almost ubiquitous. Although the severity of acne reaches its peak in the late teenage years, acne may persist into the third decade and beyond, specifically in females (Schofield and Rees, 2006:1299).

2.3 PATHOGENESIS

Three factors are implicated in the pathogenesis of acne vulgaris. Firstly, there is elevated sebum excretion. A clear relationship exists between acne severity and

sebum excretion rate. When sebum is completely absent, acne does not occur. Although sebum excretion may be high in the third and fourth decades, acne may improve. Although sebum excretion is necessary for acne development, it is not sufficient to cause acne on its own. Hormones are the main determinants of sebum excretion, particularly the main sebotrophic hormones, androgens. Progestogens also cause an increase in sebum excretion and oestrogens decrease it. This causes acne onset in the teenage years. Secondly, the bacterium *Propionibacterium acnes,* that colonises the pilosebaceous ducts, acts on lipids and forms a number of pro-inflammatory factors. Thirdly, the pilosebaceous unit becomes occluded, resulting in whiteheads and blackheads. Keratin and sebum plugging of the pilosebaceous orifice causes blackheads, and whiteheads are formed by sebum and keratin deeper in the pilosebaceous ducts. (Schofield and Rees, 2006:1299). Figure 1 is a representation of a cross section of normal skin and skin with acne.

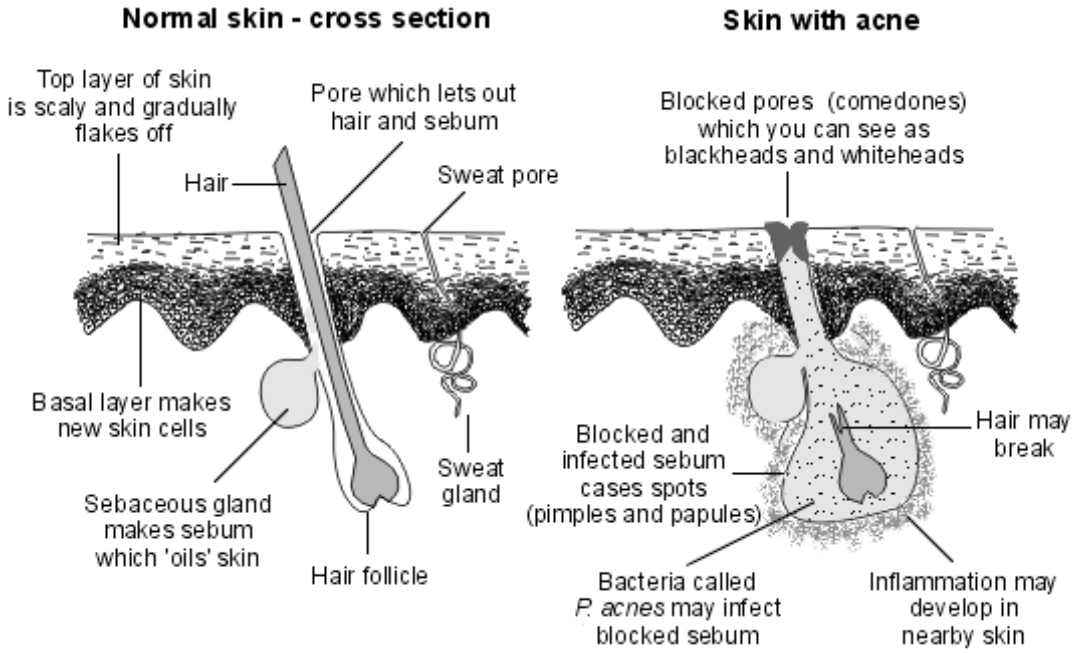

Figure 1 cross section of normal skin and skin with acne (Knot, 2012).

Propionibacterium acnes is a gram positive anaerobic bacterium and is also a commensal. This bacterium (1) forms lipases, proteases, and hydrolases that contribute to inflammation and tissue destruction, (2) causes comedonal rupture

by expressing stress proteins, (3) causes toll-like receptors to bind on keratinocytes, so that the production and release of pro-inflammatory cytokines, e.g. Interleukin1 (IL-1), increase. Hyperkeratinisation, cell adhesion, follicular obstruction and more inflammation is thought to be stimulated by IL-1 (Nguyen and Su, 2011:119). Keratinocytes associated with the innate immune response are stimulated by *Propionibacterium acnes*, the intensity of which may be influenced by either intrinsic factors of the bacteria or by the host endogenous factors (Grange, Weill, Dupin and Batteux, 2010:1085).

2.4 SIGNS AND SYMPTOMS OF ACNE VULGARIS

The clinical features of acne vulgaris are seborrhoea (greasy skin), open comedones (blackheads), closed comedones (whiteheads), inflammatory papules, nodules and cysts. Scarring can follow (Schofield and Rees, 2006:1299).

Comedones appear as whiteheads (closed comedones) and blackheads (open comedones). Whiteheads are palpable lesions which are whitish. They are 1 to 3 mm in diameter. Blackheads are similar but have a dark centre (Beers et al., 2006:942).

Papules and pustules are red in colour. They are 2 to 5 mm in diameter. In both lesions there is damage of the follicular epithelium and accumulation of neutrophils and lymphocytes. When there is rupture of the epithelium the contents of the comedone cause an intense dermal inflammatory reaction. Papules are formed as a result of deep inflammation and pustules are more superficial (Beers et al., 2006:942).

Nodules, in comparison to papules, are larger, deeper and more solid. These lesions do not have true cystic structure, but resemble inflamed epidermoid cysts. Cysts are nodules that are suppurative. Sometimes, cysts become inflamed and this results in abscess formation. The effect of long-term cystic acne is scarring.

This shows as pits that are tiny and deep (known as “icepick scars”), large pits, shallow depressions, or hypertrophic scar areas (Beers et al, 2006:942).

2.5 CLINICAL VARIANTS OF ACNE

Acne conglobata is a form of acne vulgaris that is the most severe. It affects men more than women. Patients have abscesses, draining sinuses, comedones that are fistulated, and scars that are keloidal and atrophic. Involvement of the back and chest are severe. There may be involvement of the arms, abdomen, buttocks and also the scalp (Beers et al., 942).

Acne fulminans is severe acne with fever, joint pains and markers of systemic inflammation such as raised ESR (Schofield and Rees, 2006:1300). It is an acute, febrile, and ulcerative condition. Confluent abscesses suddenly appear. This leads to haemorrhagic necrosis. There may also be leucocytosis and joint swelling with joint pain present (Beers et al., 2006:942).

Acne rosacea is a facial eruption that is persistent. The cause is unknown and it is characterised by erythema and pustules. The secretion of sebum is normal. The condition is most common in middle age. There is involvement of the cheeks, chin and central forehead. Fixed erythema and telangiectasia follows intermittent blushing. There are dome-shaped papules and pustules but no comedones are present (Schofield and Rees, 2006:1300-1301).

2.6 DIAGNOSIS

The diagnosis of acne vulgaris is made by physical examination. The differential diagnosis consists of rosacea (a condition that lacks comedones), acne induced by corticosteroid (in which no comedones are present and pustules are in the same developmental stage), perioral dermatitis, and acneiform drug eruptions. The severity of acne is graded as either mild, moderate or severe. This is based on the number and type of lesions that are present (Beers et al., 2006:942). Acne vulgaris rarely requires diagnostic investigations. Physical co-morbidities related

to classic acne are uncommon (Fried, Webster, Eichenfield, Friedlander, Fowler and Levy, 2010:9).

In addition to physical symptoms, the diagnosis of acne vulgaris is also based on history taking (Eichenfield, Fowler, Friedlander, Levy and Webster, 2010:5). The history taking should contain important points such as age of onset, nature and distribution of lesions (whether there are comedones, inflammation and scars present) progression of the disease, possible triggers and factors that relieve the condition (Nguyen and Su, 2011:119).

2.7 AETIOLOGY AND RELATED FACTORS

Acne vulgaris is associated with a multifactorial pathogenesis (Youn, 2010:10). In a study conducted by Ghodsi, Orawa and Zouboulis, 2009:2136), recognised risk factors for moderate to severe acne were increasing pubertal age, seborrhoea, premenstrual phase, mental stress, and sweet and oily food. Other factors perceived by acne patients to be aggravating factors included stress (86.1%), hot weather (77.7%), sweating (68.7%), premenstrual factors (97.6% of female patients) and cosmetics (30.0% of female patients) (El-Akawi, Abdel-Latif Nemr, Abdul-Razzak and Al-Aboosi, 2006b:840, 842, 844).

2.7.1 Androgens and sebum production

A rise in sebum secretion is known to be one of the major pathogenic factors in acne development (Youn, 2010:8). Puberty is the most common trigger of acne vulgaris. During this period, sebum production and hyperproliferation of keratinocytes are stimulated by surges in androgen (Beers et al., 2006:1942). The abnormalities of follicular keratinisation, caused by hormones and sebum, result in follicular plugging and the formation of comedones, which are the primary lesions of acne (Gibbon, 2005:191).

The production of sebum depends on local androgen levels and the sensitivity of androgen. Testosterone is converted to the active dihydrotestosterone (DHT) by two subtypes of 5-alpha-reductase which are type 1 isozyme and type 2 isozyme.

The expression of type 1 isozyme occurs in the scalp, chest and sebaceous glands, and the expression of type 2 isozyme occurs in the genitourinary tissue, dermal papillae and hair follicles (Nguyen and Su, 2011:119).

2.7.2 Genetics

Acne may be associated with a strong genetic tendency (Gibbon, 2005:191). Results of a large adult twin study suggest that acne has a strong genetic basis (Bataille, Snieder, MacGregor, Sasieni and Spector, 2002:1319). According to a study conducted by Ghodsi, Orawa and Zouboulis (2009:2136), the risk of acne severity increased with the number of family members with acne, and a mother with a history of acne influenced the acne severity the most. Biswas et al. (2010:37) stated that an association between acne and family history was found in their study.

For over 100 years, the roles of genetic inheritance and special genetic susceptibility and protective factors have been suggested. However, only in the 1990's did their identification and determination commence. So far, only a small number of genetic polymorphisms, that affect the expression and/or function of a handful of genes, have been investigated. With regards to the genetic predisposing and susceptibility factors involved in the pathogenesis of acne, the roles of a few genes have been investigated. Two major cellular processes are affected by these genes, namely, regulation of the steroid hormone metabolism or the innate immune function of epidermal keratinocytes (Szabó and Kemény, 2011:766, 771).

2.7.3 Diet

According to Gibbon (2005:191), diet has only a minor role in the aetiology of acne. However, a study conducted in Jordan, which assessed patients' perceptions of possible factors that had an effect on their acne, found that certain dietary items were listed by them as factors. Such items included nuts, chocolate, fatty food, fried food, eggs, cakes, biscuits, spices, coffee and tea (El-Akawi et al., 2006b:840).

Smith, Mann, Braue, Mäkeläinen and Varigos (2007:107) conducted a randomised trial in which they established that a low-glycaemic load diet improves symptoms in acne vulgaris.

According to Cordain (2005:89), there is a substantial body of literature that implicates diet as the most likely environmental factor underlying acne development, and diet may influence the following directly or indirectly: an increase in basal keratinocyte proliferation in the pilosebaceous duct, separation of ductal corneocytes incompletely from one another through impairment of apoptosis and subsequent pilosebaceous duct obstruction, increases in sebum production that are androgen-mediated, *Propionibacterium acnes* colonization of the comedo, and inflammation within and adjacent to the comedo.

In a study conducted by Rubin, Kim and Logan (2008), Omega 3 fatty acids and other nutrients in combination, e.g. epigallocatechin-3-gallate (EGCG), zinc gluconate, selenium and chromium improved acne inflammatory lesions and aspects of mental health. However, sample size was very small as only five subjects participated, so the results cannot be regarded as conclusive.

According to El-Akawi, Abdel-Latif and Abdul-Razzak (2006a:430, 434), low plasma levels of vitamins A and E play an important role in the acne pathogenesis and also aggravates the condition.

Therapeutic vitamins, such as vitamins A and D and their analogs, and antioxidant vitamins, such as vitamins C, E and coenzyme Q, play a huge role in skin care. Their benefits range from the improvement of acne and psoriasis to protection from environmental insults (Shapiro and Saliou, 2001:839).

Lactoferrin is an iron rich milk protein which can be isolated from whey. It has a prominent activity against inflammation and microbial infection in vitro. A 12 week double blind placebo controlled randomized clinical study was conducted to determine the dietary effect of lactoferrin-enriched fermented milk on skin surface

lipids and clinical improvement of acne vulgaris. The sample number was 56 (11 men and 17 women per group) and patients were clinically assessed by the same dermatology registrar at monthly visits (0, 4, 8 and 12 weeks) by counting acne lesions (open and closed comedones; papules, pustules and nodules). Acne severity was evaluated according to the Leeds revised acne grading system at baseline and 12 weeks. Photographs of patients were taken at baseline and 12 weeks to document efficacy. The study found that there was no alteration in skin hydration or pH in both groups. The amount of free fatty acids decreased in both groups, but triacylglycerols decreased in the lactoferrin-enriched fermented milk group only. The decreased amount of triacylglycerols in the lactoferrin group was significantly correlated with decreases in serum content, acne lesion counts, and acne grade. The authors concluded that lactoferrin-enriched fermented milk, ingested daily, ameliorates acne vulgaris with a selective decrease in triacylglycerols in skin surface lipids. Therefore, lactoferrin-enriched fermented milk could possibly be an alternative therapy or may act as an adjunct to conventional therapies in acne vulgaris treatment (Kim, Ko, Park, Kim, Ha and Cho, 2010).

Danby (2010) has studied the effect of diet on androgen metabolism and acne. He points out that the Western diet includes many dairy sources which naturally contain hormones which are androgenic. Milk contains anabolic steroids as well as precursors of dihydrotestosterone (DHT) which is a classic acnegenic androgen. The Western diet also contains foods with high glycaemic indices which affect serum insulin and insulin-like growth factor 1 (IGF-1) levels causing increased formation of androgens and acne development as a result. Danby concludes that dermatologists should advise their patients to follow a zero dairy and low glycaemic index diet.

2.7.4 Psychological effects of acne vulgaris

Acne vulgaris is a skin condition that is distressing and has significant psychological disability associated with it (Katzman and Logan, 2007:1080). Changes in acne severity can be associated with increasing stress, suggesting

that emotional stress from sources that are external may influence acne significantly (Chiu, Chon and Kimball, 2003:897). Patients with acne are affected both physically and mentally (Uhlenhake, Yentzer and Feldman, 2010:59). Acne has a huge impact on the well-being and quality of life of acne sufferers (Pawin et al., 2007:313). The short and long term psychosocial effects of acne are difficult to detect and measure. Commonly, these are life-altering and devastating. Sometimes, they are life-threatening (Fried et al., 2010:9).

In a study conducted by Uhlenhake, Yentzer and Feldman (2010:59-60), depression in acne patients was two to three times more prevalent than the general population. A reported 8.8% of patients with acne had clinical depression. Depression and antidepressant use was mostly observed in acne patients who were 18 years of age and over, with the highest percentage in the age group 36 to 64. Females formed about 65.2% of the acne patient population. Twice as many females than males had depression (females: 10.6%; males: 5.3%). Anti-acne treatment usage (topical, oral or both) was related with a lower prevalence of antidepressant use, compared to patients who received no treatment.

There are significant psychosocial effects of acne on self-esteem, particularly during the adolescent years. During the adolescent years, lowered self-esteem or body image may directly influence identity formation. Appropriate treatment of any disease should include the effects of the disease on the individual, both psychologically and socially. The focus should not be on the treatment of the disease only (Hedden, Davidson and Smith, 2008:599-600). Yosipovitch, Tang, Dawn, Chen, Goh, Chan and Seng (2007:135) found that a significant association existed between stress and the severity of acne papulopustulosa, mainly in males.

2.7.5 Relationship between acne vulgaris, psychological effects and nutritional factors

Anger is more likely to be experienced in acne patients. These patients are also at an increased risk of experiencing depression, anxiety and suicidal thoughts.

Nutrients which have been shown to influence the pathophysiology of acne are also important mediators of human behaviour, emotions and cognition, for example, zinc, folic acid, selenium, chromium and α 3 fatty acids. These nutrients influence depression, anger and/or anxiety. These nutrients together with systemic oxidative stress and an altered intestinal microflora have been involved in acne vulgaris. In conclusion, certain nutritional factors, an antioxidant defence system that is weakened and an altered intestinal microflora may interplay to cause an increased risk of psychological effects in acne vulgaris (Katzman and Logan, 2007:1080).

2.7.6 Smoking and acne vulgaris

There is an unclear relationship between tobacco smoking and acne. Varying results are evident from extensive study of the association between acne and smoking (Klaz, Kochba, Shohat, Zarka and Brenner, 2006:1749). According to Firooz, Sarhangnejad, Davoudi and Nassiri-Kashani (2005), there is no association between acne and cigarette smoking. However, a study carried out by Schäfer, Nienhaus, Vieluf, Berger and Ring (2001:102) found that acne among smokers is more frequent and severe, and follows a dose-dependent association. Schafer et al. (2001:100) also state that smoking is a clinically important contributory factor to the prevalence and severity of acne. Jemec et al (2002), as cited by Klaz et al. (2006:1750), concluded that there was no significant association between smoking and acne, in a random sample consisting of 186 subjects.

A study was conducted by Capitanio, Sinagra, Bordignon, Cordiali Fei, Picardo and Zouboulis (2010:782) to investigate the clinical features of post-adolescent acne in female acne patients and its relationship with cigarette smoking. A total of 226 females aged 25-50 and affected by acne were assessed by 3 dermatologists. The study concluded that the most common clinical form of post-adolescent acne is comedonal post-adolescent acne (CPAA) and there seems to be a strict correlation with cigarette smoking.

2.7.7 Myths and misconceptions

According to Al-Hoqail (2003:765), misconceptions and false beliefs among the youth are widespread and enduring. Therefore, in order to improve their understanding of acne, a health education program is required. Hedden, Davidson and Smith (2008:599) state that there is general lack of knowledge about acne, its causes, and its treatment, among adolescents. Brajac, Bilic-Zulle, Tkalčić, Lončarek and Gruber (2004:21) have noted that both family physicians and acne patients underestimate the impact that acne vulgaris has.

Choi, Lew and Kimball (2006:421) state that the general public believes that fewer blemishes will result when the skin is clean. However, dermatologists warn that the condition of acne can be worsened by over-washing and scrubbing. Their single-blinded, randomised, controlled clinical trial concluded that little support existed to recommend face-washing twice daily with a cleanser, in terms of efficacy and convenience, and that washing the face excessively may not be as responsible for acne as previously thought (Choi, Lew and Kimball, 2006:421, 425).

Layton (2005:44) compares certain myths associated with acne vulgaris and the reality of the condition. Myths include the following: bad hygiene causes acne, acne is contagious, greasy cosmetics and a lack of exercise make acne worse. However, according to him, the reality is that washing frequently has no effect on acne, and acne is not contagious. There is no evidence that acne is made worse by cosmetics. Finally, acne is not influenced by exercise.

2.8 ALLOPATHIC TREATMENT

Conventional treatment has two aims – decrease the uptake of androgens and decrease the keratogenesis of cells that constitute the pilosebaceous glands (Jouanny et al., 1994:274). Therapy is aimed at skin cleansing and desquamation, utilising antimicrobials, anti-androgens and follicular keratinisation control (Gibbon, 2005:191).

2.8.1 Acne preparations for topical use

Topical agents, such as Benzoyl peroxide, are recommended for patients who have minor symptoms dominated by comedones. However, evidence for the effectiveness of washes, soaps and antiseptics is not convincing (Schofield and Rees, 2006:1300).

2.8.1.1 Precipitated sulphur

Sulphur is a parasiticide and antiseptic that is mild. It possesses weak antibacterial and antifungal activity, and a desquamative action. Sulphur can be used on its own or in combination preparations. It can be combined with keratolytic agents, for example, resorcinol, salicylic acid, benzoyl peroxide, or calamine. Contact with the eyes and mouth must be avoided (Gibbon, 2005:191).

2.8.1.2 Benzoyl peroxide

The efficacy of benzoyl peroxide in acne is due to its desquamative action. It also causes a great reduction of skin bacteria and may reduce inflamed and non-inflamed lesions. Antiseptics are included in certain preparations but this does not cause increased efficacy. It is the most cost-effective treatment for acne that is mild to moderate, when combined with a topical antibiotic, in randomised controlled trials. It may cause an allergic contact dermatitis, or a common low-grade primary dermatitis in the first few weeks which is not harmful. However it can result in post-inflammatory hyperpigmentation in dark-skinned people. An example of benzoyl peroxide is Panoxyl® (Gibbon, 2005:192).

2.8.1.3 Azelaic acid

Azelaic acid is used for mild to moderate acne vulgaris. It has antimicrobial effects on *Propionibacterium acnes* and it influences follicular hyperkeratosis. Hypersensitivity and photosensitivity reactions have been noted. Another adverse effect is local skin irritation (redness, burning, itching and scaling, which may

occur at first but usually regresses. An example of azelaic acid is Skinoren® (Gibbon, 2005:192).

2.8.1.4 Abrasive agents

These may be useful as adjuncts to acne treatment. Abrasive scrub cleaners include preparations containing aluminium oxide particles or polyethylene granules. Treatment should be temporarily interrupted if irritation of the skin, such as redness and dryness, occurs (Gibbon, 2005:192).

2.8.1.5 Degreasing agents

Degreasing agents are solvents and act in several ways. They remove surface oils. They either act as surface oil absorbents or they cause a redistribution of surface oil. The irritant effects of topical therapeutics may be aggravated by degreasing agents. An example is degreasing lotion (Gibbon, 2005:192).

2.8.1.6 Anti-infectives for acne treatment

These include clindamycin (e.g. Dalacin-T®) and erythromycin (e.g. Eryderm®) and are very useful in the treatment of inflammatory acne. However, topical antibiotics can cause rapid resistance emergence and sensitivity reactions. Antagonism between erythromycin and clindamycin has been demonstrated (Gibbon, 2005:193). There has been a gradual decrease in the efficacy of topical erythromycin, probably as a result of resistance of *Propionibacterium acnes* to antibiotics (Simonart and Dramaix, 2005:395). Therefore, in order to decrease the risk of community antibiotic resistance, the use of non-antibiotic therapies are recommended (Ingram, Grindlay and Williams, 2009:351).

2.8.1.7 Topical retinoids

Topical retinoids are the mainstay of acne treatment because they target microcomedo, which are the precursors to all acne lesions. Retinoids are comedolytic and are characterised by anti-inflammatory effects (Zaenglein and

Thiboutot, 2006:1188). They include tretinoin (e.g. Retin-A®), isotretinoin (Isotrex®), adapalene (Differin®) and tazarotene (Gibbon, 2005:194).

Topical retionids are effective in the treatment of acne vulgaris that is predominated by comedones, papules and pustules. However, they are usually ineffective in treating acne with severe pustular or deep nodular cystic lesions. They normalize keratinization. Desquamation is achieved by reducing intercellular corneocyte adhesion. They inhibit the formation of comedones and therefore provide prophylactic acne treatment (Gibbon, 2005:193). Topical retinoids are suitable for initial and maintenance therapy and many patients achieve adequate disease control with the assistance of this drug class (Knutsen-Larson, Dawson, Dunnick and Dellavalle, 2012:102).

There are many adverse effects which include transient stinging or burning, extreme redness, dryness, blistering or oedema, increased susceptibility to sunlight, and hyper- or hypopigmentation. Adverse effects mostly occur due to incorrect use (Gibbon, 2005:193).

2.8.2 Acne preparations for systemic use

2.8.2.1 Isotretinoin

The gold standard treatment for severe acne is oral isotretinoin monotherapy (Ingram, Grindlay and Williams, 2009:351).

Isotretinoin (e.g. Roaccutane®) is used mainly for the treatment of intractable acne. The exact mechanism by which isotretinoin acts is unknown. Isotretinoin decreases the secretion of sebum by causing a reduction in the size of the sebaceous glands and inhibiting the activity of sebaceous glands. It also modifies follicular keratinisation and possesses anti-inflammatory and antibacterial activity (Gibbon, 2005:194).

The side effects of isotretinoin are mostly dose-related and include skin rashes, hair loss that is reversible, nail dystrophies, fragile and thin skin, exfoliation of the

palms and soles, raised intracranial pressure (visual disturbances and headaches), musculoskeletal pain, irritation of the gastrointestinal tract (nausea and vomiting), hepatitis, rise in serum triglycerides, malaise, sweating and drowsiness (Gibbon, 2005:194). Other side effects include drying of the skin and mucous membranes, teratogenicity, and various forms of psychopathology, e.g. depression, suicide attempts and psychosis (Schofield and Rees, 2006:1300; Kontaxakis, Skourides, Ferentinos, Havaki-Kontaxaki and Papadimitriou, 2009). Treatment with oral isotretinoin has been associated with central retinal vein occlusion in an adolescent male with a minor predisposition for thrombosis (Labiris, Katsanos, Karapetsa, Mpanaka and Chatzoulis, 2009).

Research was conducted by Azoulay, Blais, Koren, LeLorier and Bérard (2008:526) to determine whether isotretinoin causes an increase in the risk of depression in patients with acne. This was the first controlled study that found an association between isotretinoin use and depression. The depression risk increases almost threefold, in patients with no previous history of depression, after isotretinoin exposure. This study concluded that serious consequences can result from depression. Therefore isotretinoin users should be closely monitored.

Several international experts recommend that patients with less severe forms of acne should also be treated with oral isotretinoin, particularly patients with scarring, massive psychological stress, or patients unable to respond to conventional treatment, not only patients with severe acne vulgaris (Rigopoulos, Larios and Katsambas, 2010:24).

2.8.2.2 Oral antibiotics

The main oral antibiotic is oxytetracycline. Minocycline is used should the response to oxytetracycline be inadequate or due to the ease of dosing (Schofield and Rees, 2006:1300). Tetracyclines, erythromycin and co-trimoxazole are the antibiotics that are used to control moderate to severe acne. Patient response and tolerance determines antibiotic choice. If a patient does not respond to an antibiotic, this does not necessarily mean that the other antibiotics

will also be ineffective. Co-trimoxazole is especially efficient in seborrhoea cases. Prolonged antibiotic use can interfere with the normal body flora leading to pathological overgrowth of organisms (Gibbon, 2005:195). Therefore, physicians should avoid long-term antibiotic monotherapy in the treatment of acne (Knutsen-Larson et al., 2012:104).

2.8.2.3 Oral contraceptives

Therapies with an anti-androgen effect, e.g. combination oral contraceptive pills, can be useful in managing acne (Harper, 2005:103). In female patients, a significant contribution has been made to the management of acne through utilisation of oral contraceptive preparations consisting of low anti-androgenic potential in female patients, e.g. cyproterone acetate is an anti-androgen and is useful when used in combination with low-dose oestrogen. Oral contraceptives that contain the newer progestogens, desogestrel, gestodene and norgestimate may be effective when combined with low-dose oestrogen. Pregnancy, lactation and thrombosis predisposition are contraindications for the use of oral contraceptives (Gibbon, 2005:195).

In females, hormone therapy can be effective regardless of whether there is an abnormality of serum androgens. Women with persistent inflammatory papules of usually the lower face and neck seem to respond best to such therapy. Commonly, these women report that there is premenstrual flare up of their acne and consists of a few inflammatory lesions that are tender and deep-seated (Layton, 2005:45). However, Junkins-Hopkins (2010:488) states that oral contraceptives should be used in patients who have evidence of hormonal acne and in whom conventional non-hormonal therapy has failed. She also states that using an oral contraceptive before an isotretinoin course is recommended, mainly due to it being an effective form of birth control.

2.8.3 Other treatment considerations

The incision and draining of cysts can be accomplished under local anaesthetic. The resolution of stubborn cysts is made quicker by intralesional triamcinolone

injections (0.1-0.2 ml of a 10 mg/ml solution). Scarring that follows acne is seen numerous times. However, scarring among patients who receive adequate care is seen less commonly. Acne scars that are small and deep can be excised. However, carbon dioxide laser can be used to treat acne scars that are more extensive and shallower (Schofield and Rees, 2006:1300).

In a study conducted by Ozolins, Eady, Avery, Cunliffe, O'Neill, Simpson and Williams (2005), mild to moderate inflammatory acne responded unfavourably to antimicrobial treatment, and the most cost effective therapy for facial acne was benzoyl peroxide and the least cost-effective was minocycline. In terms of clinical efficacy, topical antimicrobials worked at least as well as oral antibiotics. Muizzuddin, Giacomoni and Maes (2008:e183) state that although acne can be treated with benzoyl peroxide or retinoids, milder agents are preferred.

Acne vaccines that modulate host immune responses to *Propionibacterium acnes* are unavailable. However, there is promise for acne therapy with regards to immunisation with *Propionibacterium acnes* (Kim, 2008:2353). A potential vaccination that targets the cell wall-anchored sialidase of *Propionibacterium acnes* is being studied. Anti-sialidase antibodies suppress inflammation induced by *Propionibacterium acnes* and neutralise the cytotoxicity of *Propionibacterium acnes* in the sebocytes (Nguyen and Su, 2011:125).

Adjunctive therapies for acne include superficial chemical peels, laser treatment, and photodynamic therapy. However, they have only temporary sebosuppressive effects (Youn, 2010:8). Some benefit has been noted from the treatment of acne with several forms of light sources, e.g. laser and photodynamic treatment, but concerns still exist about the response duration and post-inflammatory pigmentation (Ingram, Grindlay and Williams, 2009:353). The use of photodynamic therapy is limited by availability, adverse effects and cost, (Williams, Dellavalle and Garner, 2012:361). However, according to Wainwright, Smalley and Flint (2011:5), several criteria make the use of photosensitising agents attractive. These are broad-spectrum efficacy, absence of resistance mechanisms, speed at which bacteria are killed, and penetration of tissue of long

wavelength (far-red) light. Elman and Lebzelter (2004:139) state that mild to moderate inflammatory acne can be safely and effectively treated by laser and light-based therapy, and improvement of acne produced by light therapy can be compared to the effects produced by oral antibiotics, but offers resolution that is faster and lesser side effects, leading to patient satisfaction.

Fullerene is a carbon molecule that is spherical and possesses a strong radical sponge activity. It has antioxidant activity. In a study conducted to test the effectiveness of fullerene gel on acne vulgaris, it was concluded that it is safe and useful, as a skin care product, for controlling acne vulgaris, that is, fullerene gel may assist to control acne vulgaris with benefit to skin care (Inui, Aoshima, Nishiyama and Itami, 2011: 238, 240).

Treatment of acne vulgaris at any age depends on the type of acne and involvement severity (Friedlander, Baldwin, Mancini, Yan and Eichenfield, 2011:S11). However, the majority of young people with acne do not seek assistance from primary health-care services (Purdy, Langston and Tait, 2003:527).

Since acne treatment and pathogenesis is complex, there is a need for ongoing research so that best-practice guidelines are established (Knutsen-Larson et al., 2012:104).

2.9 NATUROPATHIC DIET APPROACH FOR ACNE TREATMENT

The diet should be simplified by eating food as close to the way it comes from nature. This means that food additives such as flavourings, colourings, and preservatives should be eliminated. Foods should be minimally processed. Whole grains are better than breads which are manufactured from the same grains. Common food triggers such as sugar, alcohol, chocolate or fried foods should be avoided (Baral, 2009:144).

The vegetable intake should be increased. Ideally, vegetables should make up 30% to 50% of the diet. If used in moderation, fruits are commonly good additions. However, too much sugar from fruits can be just as bad as too much refined sugar. Essential fatty acids from fish and flax oils that replace trans-fatty acids and hydrogenated oils seem to be of benefit (Baral, 2009:144).

An allergy elimination diet is recommended for severe acne. The most common food allergies are removed by this diet, which includes dairy, soy, eggs, chocolate, nuts, citrus fruits, wheat, and corn. This diet can be used in the most committed patients only and is an extreme diet, especially for most adolescents (Baral, 2009:144).

2.10 HERBAL TREATMENT

Herbal Medicine is also referred to as Herbalism or Botanical Medicine. Herbs are used for their medicinal value. A herb is a plant or a part of a plant known for its medicinal, aromatic or savory qualities. A variety of chemical substances, which act upon the body, are produced by herb plants. Many modern day drugs used commonly are of herbal origin. Some are produced from plant extracts while the others are synthesized to mimic a natural plant compound. Herbal Medicine is a common element in Ayurvedic, homoeopathic, naturopathic, traditional oriental, and Native American Indian medicine. An example of a herb plant is St. John's Wort, which is widely used in the treatment of mild depression (Herbal medicine: Introduction, 2007).

A study examined acne vulgaris treatment with new polyherbal formulations consisting of Clarina cream and Purim tablets. One hundred and five acne vulgaris patients with active lesions participated in a clinical trial. Purim tablets were given to patients to take daily for four weeks at a dosage of 2 tablets twice a day. At the same time patients were told to apply Clarina cream to the affected area consisting of acne lesion twice a day for four weeks. Grades I (mild acne with papules only) and II (moderate acne consisting of papules and comedones) showed excellent response to treatment, after four weeks of treatment. Grade III

acne (severe acne with huge papules and pustules) also showed a significantly positive response, in papule and pustule healing. Adjuvant treatment was needed by the Grade IV acne (acne that is very severe and consisting of papules, pustules and cysts). All patients showed no local or systemic side effects. The researchers concluded that Clarina cream and Purim tablets were useful in the treatment of various degrees of acne vulgaris (Anand Kumar and Sachidanand, 2001:138).

In a study conducted by Tsai, Tsai, Wu, Tseng and Tsai (2010:964, 968), it was demonstrated that duzhong and yerba mate herbal extracts had antimicrobial effects and anti-inflammatory effects against *Propionibacterium acnes*, and may therefore be used as therapeutic agents in the treatment of acne vulgaris. However, the mechanism of duzhong and yerba mate remains unknown. Chomnawang, Surassmo, Nukulkarn and Gritsanapan (2005:330) state that *Garcinia mangostana,* a Thai medicinal plant, strongly inhibited *Propionibacterium acnes* and *Staphylococcus epidermis*, and could possibly be an alternative treatment for acne vulgaris.

Acne has traditionally been treated with liver-supporting herbs, e.g. burdock (*Arctium lappa*) and dandelion root (*Taraxacum officinalis*). They can be eaten as food, added to salads, or drank as tea. However, they are bitter and therefore not very pleasant to taste. The preferred forms include liquid extracts or pills (Baral, 2009:144).

In research conducted by Orafidiya, Agbani, Oyedele, Babalola, Onayemi and Aiyedun (2004:15), it was found that aloe vera gel caused an enhancement in the anti-acne properties of *Ocimum gratissimum* oil (an essential oil of *Ocimum gratissimum* Linn leaf). The oil alone, or when combined with aloe vera gel, is more effective than 1% Clindamycin in treating acne vulgaris.

A randomised, double-blind placebo controlled clinical trial was conducted to determine the efficacy of 5% topical tea tree oil gel in mild to moderate acne vulgaris. There were 60 patients that participated in the study. These patients

were randomly divided into 2 groups of 30 patients each. Patients had to apply the drug or placebo on the affected area twice daily for a period of 20 minutes and then wash it off with tap water. The treatment period was 45 days and patients were seen every 15 days. This was to evaluate the acne lesions and any side-effects. The efficacy of treatment on the severity of acne was determined by using both total lesion count (TLC) (papules + pustules + comedones + nodules) and acne severity index (ASI), It was found that 5% tea tree oil was significantly effective in the treatment of mild to moderate acne vulgaris, i.e. it was effective in reducing both inflammatory and non-inflammatory lesions of acne vulgaris (Enshaieh, Jooya, Siadat and Iraji, 2007)

2.11 HOMOEOPATHIC TREATMENT AND RESEARCH

Homoeopathy is widely accepted which indicates that there are patient needs which cannot be satisfied by the effectiveness of modern therapeutic drugs alone. Patients are looking for the following: understanding, emotional acceptance, counselling, comfort and compassion. This is in addition to or even instead of a skilled prescription from state-of-the-art medicine (Smolle, 2003:96).

Homoeopathy is one of the most common alternative methods used in patients with dermatologic diseases (Smolle, 2003:93). There are many individuals with apparently incurable skin diseases that use complementary and alternative medicine. Recently, homoeopathy has become increasingly popular in patients with skin disease (Itamura, 2007:115).

In taking a case, the symptoms (psychological, physical and psychosomatic) and effects of skin diseases are considered to be inextricably linked. Homoeopathic treatment involves individualisation and can produce a good response in patients with chronic skin disease. Therefore, the holistic approach of homoeopathy alongside conventional treatment may be considered a useful strategy (Itamura, 2007:115).

2.11.1 Homoeopathic treatment in general

Homoeopathy is based on the Law of Similia, the most fundamental law of homoeopathy. It states that the symptoms which the sick experience are not the disease but a reaction of the body's defence mechanism which mobilises its resources to counteract the morbific influence. An organism under stress basically reacts by producing symptoms. These symptoms act like individualistic clues to the homoeopath, to assist the organism. Therefore, the remedy choice is based on the principle of "*Similia Similibus Curentur*". The remedy must have the ability to produce symptoms that are most similar to the disease to be cured in a healthy individual (Chauhan and Gupta, 2007:11). In homoeopathy, the life force or vital force is a force, power or energy that enlivens the material organism (O'Reilly, 1996:323). This immaterial being carries out all the functions of life and without this energy the material organism is capable of no sensation, function or self-preservation (Chauhan and Gupta, 2007:12).

Homoeopathic treatment is "long lasting and non-toxic" (Jouanny et al., 1994:274). Homoeopathy is a natural system of treatment which aims to maintain equilibrium both within the body (homeostasis) and in the entire ecosystem (Chauhan and Gupta, 2007:74).

The homoeopathic treatment of acne can be difficult as the condition may be long-standing (chronic) and as a result resolution may take time. The classical approach to homoeopathic treatment of acne involves the ability to select the single homoeopathic medicine whose materia medica description very closely matches the patient symptom picture. Important indications for the simillimum are the patient's mental and emotional state. After selection of the medicine, it can be given through the oral route or sublingually in a 30CH potency two to three times a week. In more serious acne cases, patients may benefit from using a potency that is higher, for example, 200CH potency, on the same schedule (Levatin, 2009:143).

An example of protocol for the management of a patient on conventional treatment who begins with homoeopathic treatment is provided by Levatin (2009:143), who is a medical paediatrician and homoeopath. If a patient is on conventional treatment before starting homoeopathic treatment, the treatment should be maintained for one month after the homoeopathic medicine was introduced. At that time, there can be slow reduction or withdrawal of conventional treatment, if improvements from the homoeopathic treatment are noted. Topical care with natural skin care products and/or dietary measures are suitable homoeopathic treatment adjuncts (Levatin, 2009:143).

Morrison (1998:472, 473) explains many important remedies for the treatment of acne. Among these are four of the remedies used in the complex utilised in this study – *Kalium bromatum, Silicea, Sulphur* and *Thuja occidentalis*. Morrison lists the main remedies for acne as being:

- ***Calcarea silicata*** – This remedy is commonly used for very persistent forms of acne. Lesions are painful and itchy, and better for warmth.
- ***Calcarea sulphurica*** – This remedy is indicated for acne that is severe, which persists sometimes in one location for weeks. A yellowish and creamy pus oozes from the lesions.
- ***Hepar sulphuris*** – Pimples are painful, sensitive and small. Comedones and suppurative lesions are present. Multiple lesions exist in crops.
- ***Lachesis mutis*** – This remedy is indicated for acne that is aggressive. Large numbers of large pimples appear on the face. The skin is purple near the pimples. Lesions are purple in colour. A purple scar is left behind in the skin with no pitting, when pimples resolve.
- ***Mercurius*** (Morrison does not state which *Mercurius*) – Indicated for acne where a large amount of pus shows through the skin. Pustules appear on a bed of red skin and can easily discharge. There can be nodules that are blue-red and do not have any pus at all. Near the lesion, there is a purple areola present. Small pimples surround a large cyst. Skin is waxy, pale and transparent.

2.11.2 The potency scale

Hahnemann progressively reduced the dose of a substance by diluting it on a definite scale. This was due to Hahnemann's attempt to reduce the severity of aggravation and this method became known as "potentisation". Crude drugs act on living organisms in three ways, which are mechanical, chemical and dynamic. Potentisation removes the mechanical and chemical aspect but enhances the drug's dynamic properties. Potentisation is peculiar to homoeopathy, and reduces the crude drug substance but increases the qualitative, medicinal or therapeutic property of the drug. Potency is the unit of drug strength. Three scales are used in the preparation of potencies, namely, the decimal scale, centesimal scale and fifty millesimal scale (Chauhan and Gupta, 2007:50).

2.11.2.1 The decimal scale

The decimal scale was introduced by Herring. In this scale, the first potency contains one tenth part of the original drug and each succeeding potency contains one tenth part of the potency preceding it. It is denoted by suffixing the letter 'X' to the number indicating the potency (Chauhan and Gupta, 2007:50).

2.11.2.2 The centesimal scale

The centesimal scale was introduced by Hahnemann. In this scale, the first potency contains one hundredth part of the original drug and each succeeding potency contains one hundredth part of the potency preceding it. The potency is denoted by suffixing the letter 'C' (or "CH") to the number indicating the potency (Chauhan and Gupta, 2007:50).

2.11.2.3 The fifty millesimal scale

The fifty millesimal scale was introduced by Hahnemann and is based on the instructions given in the 6th edition of his book *Organon of Medicine* (Chauhan and Gupta, 2007:51). Potentised medicines are prepared using a dilution ratio of 50000 parts of dilutant to 1 part medicinal substance. Also known as LM potencies (O'Reilly, 1996:309).

2.11.2.4 Methods of potentisation

The potentisation process is carried out by two methods.

2.11.2.4.1 Trituration

The main objective of trituration using a pestle and mortar is to reduce the size of the particles of a dry or crude medicinal substance to a finer degree and to homogenously mix them with the vehicle.

2.11.2.4.2 Succussion

This is the potentisation process for all soluble substances, be it in water or alcohol. Except in a few cases, alcohol is used as a vehicle in most preparations. When water soluble substances attain a 3CH attenuation by trituration, they are converted to alcoholic preparations. The technique used is to take one part of the drug substance and add it to nine parts of the vehicle in a glass vial which is clean, filling it up to 2/3rd of the bottle (Chauhan and Gupta, 2007:51).

Ten or one hundred downward strokes are given either on the palm of the hand or any soft and firm surface, after carefully corking the bottle. A fresh bottle is utilised each time. This takes the drug-vehicle mixture in the bottle to the first decimal potency level, 1X or 1D. A similar process, with the drug vehicle is used to give the centesimal 1CH potency, i.e. to take one part of the drug substance and add it to ninety-nine parts of the vehicle (Chauhan and Gupta, 2007:51).

2.11.3 Safety of homoeopathic medicines

Currently there is no mechanism in South Africa for registering individual homoeopathic medicines, but they are recorded in the Chiropractors, Homoeopaths and Allied Health Professions Second Amendment Act (Department of Health, 2000) as being the medicines used by homoeopaths to treat their patients. In August 2011, the Department of Health (2011) published

for comment guidelines which will govern the regulation of Complimentary Medicines, including homoeopathic medicines.

Homeopathic medicines are generally regarded as very safe because of the high dilutions used. However, some adverse events have been described in the literature (Thompson, Barron and Spence, 2004:203). Dantas (2000) (as quoted by Thompson, Barron and Spence, 2004:204) found that the overall incidence of adverse events from available literature was 9.1 in the homoeopathic group and 6.17 in placebo group, i.e. adverse events/aggravations are more common in verum groups. The European Council for Classical Homeopathy (ECCH) recently published a paper entitled *The safety of homeopathy*. After considering various studies on the matter, they concluded that homoeopathic medicine may provoke adverse events (AE), but that these are generally mild and transient. No cases of serious adverse events (SAE) or serious adverse drug reactions (Serious ADR) were found, which means that no cases were found resulting in hospitalisation, life-threatening situations, persistent or significant disability/incapacity or congenital anomaly/birth defect. AE were primarily headaches, but also other localised pain, dryness of skin and eruption, eye irritation, digestive problems (upset stomach, vomiting), feelings of heat, agitation, and psychological symptoms such as increased irritability and feelings of depression (European Council for Classical Homeopathy, 2009:11).

Thompson, Barron and Spence (2004:204) state that one of the best known remedy reactions is the homoeopathic aggravation. They define this as a brief worsening of the presenting symptoms occurring close to the time of taking the remedy and is either followed by the symptoms settling again to their previous state or by an overall improvement of symptoms. This is regarded as evidence that the patient is sensitive to the medicine and is not considered an adverse effect.

2.11.4 Homoeopathic research

A study was conducted to determine how effective individualised homoeopathic treatment was on dermatological complaints in a public outpatient clinic. Dermatological complaints included atopic dermatitis, psoriasis, chronic urticaria, acne, etc. Forty nine patients fulfilled the inclusion criteria. Patients from the study were followed up for a minimum period of 3 months and assessed in the follow-up consultations by means of clinical evaluation (anamnesis, physical exam, graphical record and complementary exams), and the Portuguese version of the Dermatology Quality of Life Index (DQLI) at the initial visit, and at 1, 3 and 6 months after initiation of treatment. It was concluded that individualised homoeopathic treatment was effective in 59% of patients from the study. Also, dermatological complaints improved significantly with improvements of the psychological and general state. Other pathological features did not emerge, i.e. there was no evidence of suppression (Waisse-Priven, Jurj, Lima Thomaz, Tierno, Filho, Sos and de Souza, 2009:149, 151, 152).

McDavid (1994) treated acne vulgaris using the simillimum in a double blind placebo controlled clinical trial, with 15 participants in the simillimum group and 15 in the placebo group. Participants were on treatment for 4 months which included 5 consultations and assessed according to the Leeds grading and counting techniques. Participants also had to complete a questionnaire regarding perception of the effects of treatment. There was a statistically significant improvement in the clinical manifestations of acne in the simillimum treatment group. The most prescribed remedies were *Sulphur iodatum* (22 times) and *Kalium bromatum* (18 times).

Lee (1997) determined the role of a homoeopathic complex (*Silicea* 30CH, *Selenium* 9CH, *Hepar sulphuris* 30CH, *Kalium bromatum* 9CH, *Arctium lappa* 3CH, *Pulsatilla* 30CH) in the treatment of acne vulgaris in a double blind placebo controlled clinical trial with 18 participants in the experimental group and 16 in the placebo group. Participants were treated for 2 months with 5 consultations and

assessed according to the Leeds counting technique, in terms of a reduction in the total number of lesions. There was no significant improvement between groups as well as within groups.

Van Niekerk (1999) described the relative effectiveness of miasmatic treatment as opposed to simillimum treatment in the treatment of acne vulgaris, in terms of the Leeds counting technique. The homoeopathic treatment was measured in terms of a reduction in the total number of lesions. There were 18 participants in the simillimum group and 17 in the miasmatic group. There was no statistically significant difference in lesion reduction between groups, i.e. both showed a similar reduction. Van Niekerk concluded that miasmatic treatment was as effective as simillimum treatment. However, there was no placebo group so one cannot assess whether the improvements were due to the treatment effect or the placebo effect.

Govender (2003) investigated the effectiveness of a herbal complex (*Arctium lappa*, *Berberis aquifolium, Echinacea purpurea* and *Taraxacum officinale*) as compared to a homoeopathic simillimum in the treatment of acne vulgaris. The herbal complex group consisted of 15 participants and the simillimum group 15 participants. The treatment period was 9 weeks and consisted of 4 consultations. The effectiveness of the treatment was assessed according to a perception questionnaire, visual tactile grading and the Leeds counting technique. Both groups showed a similar, statistically significant, reduction in acne lesions. It was concluded that the herbal complex worked as well as the simillimum. However, there was no placebo group so one cannot assess whether the improvements were due to the treatment effect or the placebo effect.

Bekker (2004) investigated the effect of Testis Compositum® in the treatment of acne vulgaris. Testis Compositum® contains 16 homoeopathic remedies, 5 suis organ preparations*, Acidum ascorbicum* D6 and *Cortisonum aceticum* D13. A total of 28 participants completed the study, where all participants made up the control group for the first 2 weeks and then the experimental group for the remaining 6 weeks. The efficacy of the treatment was assessed according to

facial lesion counts of acne lesions (inflamed, non-inflamed and nodulocystic), comparing each participant's condition with their baseline photographs, graded 0 to 6, and facial skin signs and symptoms (assessed by interviewing and physical exam) graded from 0 to 5.The study concluded that Testis Compositum® had a significant effect in improving acne vulgaris.

Nijland (2005) conducted a in a double blind placebo controlled clinical trial on the use of *Kalium bromatum* 30CH in the treatment of acne vulgaris. The experimental group consisted of 15 participants and the control group consisted of 15 participants. Participants were treated for 4 weeks with 3 consultations and assessed according to the Leeds counting technique. The study concluded that *Kalium bromatum* was not effective in the treatment of the clinical manifestations of acne vulgaris.

2.11.5 The homoeopathic complex utilised in this study

The materia medica of the remedies contained in the homoeopathic complex utilised in this study is as follows:

- ***Kalium bromatum***: Acne of the face, cheeks and forehead, and pustules. Itching in acne (Vermeulen, 2001:538). Aggressive acne that begins in the teen years and never ceases. Large, bluish red pimples. Cysts that are large and indurated, characterised by red areola and yellow, purulent heads (Morrison, 1998:473).
- ***Natrum muriaticum***: Face is oily and shiny, as if greased. Eruptions that are dry, especially on the margin of hairy scalp. It affects the hair follicles (Vermeulen, 2001:688).
- ***Selenium***: Comedones and surface of skin is oily (Vermeulen, 2001:866).
- ***Sulphur***: Pimply eruptions and pustules. Black comedones occur on the face, especially on the forehead, nose, upper lip and chin (Vermeulen, 2001:923).
- ***Thuja occidentalis***: Acne with very oily skin. There are pustules with sunken centres (Morrison, 1998:474). Face with greasy skin (Vermeulen, 2001:960).

All remedies in the complex were prepared at a 9CH potency. Vithoulkas (1998:214) states that in general, the more severe the state of the physical pathology, the lower the potency utilised in the initial prescription. He also states some homoeopaths combine medicines, with each medicine covering a fragment of the case, should they not see a medicine covering the totality of symptoms. Jones (2012) states that remedies in combination products may function together to strengthen supporting organs so that there is speed in response and recovery.

2.12 ACNE VULGARIS AND PATIENT EDUCATION

Clayton and Tom (2010:131) state that a detailed history taking, treatment individualisation and the reinforcement of appropriate use optimises outcomes and therapy response while also causing a decrease in the unwanted adverse effects and negative impact of acne.

According to Zaenglein and Thiboutot (2006:1197), the most important tool in effectively managing acne involves the ability of the clinician to educate and listen to the patient, and to work together with the patient to provide the best treatment for the individual.

Ramanathan and Hebert (2011:337) recommend the following regarding patient education:

- Wash the skin by using a mild, non-drying cleanser. Washing or scrubbing the face regularly should not be encouraged.
- Hair and skin care products, such as cosmetics, sunscreens and moisturisers, that are labelled non-comedogenic or non-acnegenic, should be selected.
- Patients must not traumatise their acne lesions, e.g. squeezing or picking acne lesions. They should also not use athletic gear that is occlusive, to prevent scarring.
- Patients should be informed that treatment is a process that is long term. In order to control initial symptoms, several weeks to months of treatment are required. Ongoing maintenance therapy should follow.

- Before the skin can clear, dryness and irritation can produce a potential for initial worsening. Patients should be warned of this. A non-comedogenic moisturiser should be used to moisturise for dryness and a sun block should be used.
- There must be a discussion about maintenance therapy with the patient as acne vulgaris has a tendency to recur without ongoing maintenance therapy.
- Patients must be reassured that diet, e.g. chocolate and soda, does not worsen their acne.

Acne can cause a massive financial burden to the community. The burden of the disease can be reduced by effective treatment. However, poorly considered therapy can result in ineffective treatment, be costly and also aggravate non-compliance. The key strategy to maintain response to treatment is compliance. Compliance must be encouraged by simplifying medication regimes, positive reinforcement of patient behaviour, and written education. Treatment regimens must include considerations of the patient as an individual, noting limitations and potential side effects of every therapeutic option (Nguyen and Su, 2011:119, 125). Treatment regimens must also consider the largely varying differences among patients of different ages, ethnic and cultural backgrounds (Baldwin, Friedlander, Eichenfield, Mancini and Yan, 2011:S15).

2.13 THE LEEDS COUNTING TECHNIQUE

The Leeds acne counting technique assesses facial lesions only (Burke and Cunliffe, 1984:87-92). Lesions are divided into non-inflamed and inflamed lesions. Non-inflamed lesions are the blackheads and whiteheads. Inflamed lesions are superficial (papules and pustules), which are from 0.1 cm to 0.5 cm, or deep (nodules, cysts and deep pustules) which are 0.5 cm or larger. Macules represent the resolving phase of either superficial or deep lesions, and are included with inflamed lesions in the counting process.

The Leeds counting technique is used for detailed work in therapeutic trials, and is simple and reproducible when it is carried out with attention to detail (Burke and Cunliffe, 1984:83).

The Leeds counting technique was used in this study. Response to treatment was assessed in terms of a reduction in the total number of lesions. Previous studies at Technikon Natal/Durban University of Technology that used the Leeds counting technique were the clinical trials conducted by McDavid (1994), Lee (1997), Van Niekerk (1999), Govender (2003) and Nijland (2005), with statistically significant reductions recorded by McDavid (1994), Van Niekerk (1999) and Govender (2003).

CHAPTER 3
MATERIALS AND METHODS

This study was a double blind placebo controlled clinical trial.

3.1 POPULATION, SAMPLE, PATIENT RECRUITMENT AND SELECTION

The population is all persons between the ages of 13 and 35 with acne living in the Greater Durban area. Thirty seven participants were recruited. The final sample size was 34, stratified for gender. Three participants dropped out during the course of the study, but were replaced so as to maintain a sample size of 34. One participant dropped out from the experimental group on the basis that he experienced flu-like symptoms (headaches and dizziness) which he considered to be side effects caused by the homoeopathic acne complex. Two participants from the placebo group dropped out as a result of not reporting for their second consultations.

Participants were recruited by means of convenience sampling. In the convenience sampling method, the researcher studies elements of a population that can be studied with the greatest convenience. The advantages of convenience sampling are that it is cheap and can be quickly executed. Disadvantages are that it can lead naturally to sampling error and bias. An example of convenience sampling is a sample that consists of volunteers (Steyn, Smit, du Toit and Strasheim, 1994:39).

Advertisements in the form of posters (Appendix A) were placed on notice boards in shops, pharmacies, health shops, hospitals, schools, Durban University of Technology and other tertiary institutions, as well as other public places in the Greater Durban area. Permission was obtained before erecting the advertisements. Smaller versions of the poster (Appendix A) were distributed as handouts.

Immediate family members and close friends of the researcher were not accepted into the study.

The age group of 13 to 35 was chosen as the age range because previous acne studies at Technikon Natal/Durban University of Technology have utilised a similar age range, e.g. Lee (1997) selected participants between 14 and 30 years of age, and Govender (2003) selected participants between 18 and 40 years of age. The majority of acne sufferers are teenagers (Williams, Dellavalle and Garner, 2012).

The gender stratification of the sample was 18 females and 16 males, based on a study conducted by Collier et al. (2008:58) who determined the prevalence of acne in adults, as reported by participants. They found that acne affected males and females almost equally during their teenage years (68.5% of males and 66.8% of females). However, between the ages of 20 and 29, acne affected 50.9% of females and 42.5% of males, and between the ages of 30 and 39 acne affected 35.2% females and 20.1% of males. Thus, after the teenage years, the number of females with acne was significantly higher than the number of males in all age groups (Collier et al., 2008:58).

Race stratification of the sample was not undertaken. According to Kimball (2008), the epidemiology of acne and race is not well studied because of problems such as determining degree of skin colour. The author goes on to say that although the prevalence and severity of acne varies across racial and ethnic groups, the differences do not appear to be huge.

The following simplified classification was used to diagnose and select participants for this study, according to the BMJ Evidence Centre (2010):

- Mild: comedones are the main lesions. Papules and pustules may be present but are small and few in number (generally < 10).

- Moderate: moderate numbers (10 to 40) of papules and pustules. Moderate numbers (10 to 40) of comedones are also present. Sometimes mild truncal disease.
- Moderately severe: numerous papules and pustules (10 to 40) usually with many comedones (40 to 100) and the occasional (up to 5) larger, deeper nodular inflamed lesions. Widespread affected areas usually involving face, chest and back.
- Very severe: nodulocystic acne and acne conglobata with severe lesions; many large, painful nodular/pustular lesions along with many smaller papules, pustules, and comedones.

Participants were selected and randomly assigned to an experimental (homoeopathic complex) group or control (placebo) group according to gender stratification, only after the participant read the information letter (Appendix B1: English; Appendix B2: Zulu), met the inclusion and exclusion criteria, and signed the informed consent form (Appendix C1: English; Appendix C2: Zulu). A child assent form (Appendix D1: English; Appendix D2: Zulu) was available to children under 18 years of age. Parents/guardians were required to grant their children permission to participate in the clinical trial, as evidenced by their co-signing the child assent form. Participants were also required to fill in a Confidential Patient Information Form (Appendix E1: English; Appendix E2: Zulu) when they first arrived at the Homoeopathic Day Clinic, which recorded demographic information. The case notes (Appendix F) and acne assessment sheet (Appendix H) carried a participant number only.

After selection, participants were randomly assigned to an experimental (homoeopathic complex) group or control (placebo) group according to gender stratification. Neither the researcher nor the patient knew who belonged to the experimental or control group. This information was revealed to the researcher and participants after all data had been collected and the study was completed. The Clinic Director generated the randomisation sheet. This sheet was kept in a locked cupboard in the reception area of the Clinic. At the end of the first

consultation for each participant, the dispenser entered the name of the participant in the next consecutive number on the sheet, and dispensed the medication associated with that number. The Clinic Director unblinded the randomisation sheet at the end of the clinical trial. However, if necessary, he was able to unblind a particular participant number during the trial if that participant experienced symptoms which were deemed to be adverse events.

A placebo is a pharmacologically inert substance, having no physiological action. The following therapeutic situations may require a placebo: as a control in the scientific evaluation of drugs, after the first prescription particularly in chronic cases, to please by psychological means, and as a vehicle for cure by suggestion (Chauhan and Gupta, 2007:53).

A placebo group in a double blind, randomised, controlled trial is the most rigorous test of the efficacy of treatment for a medical therapy evaluation. Trials with a placebo group offer the opportunity for outcomes to be compared under maximal “treatment separation” conditions (a group that is exposed to the investigational treatment versus a group that is not exposed to the investigational treatment). This increases the likelihood of determining beneficial and/or harmful treatment-related effects. However, it is also important to note that trials with placebo groups may produce indirect benefits, e.g. participants in the placebo control group frequently benefit from the attention they receive from investigators of the study and staff. They also benefit from the ancillary treatments and the diagnostics which they receive as part of the trial (Castro, 2007).

Randomised controlled trials are the most rigorous way to determine whether a cause-relation effect is present between treatment and outcome. Random allocation ensures that there are no systematic differences between intervention groups in factors, known and unknown, which may affect outcome (Sibbald and Roland, 1998).

Double-blinding in a randomised controlled trial enasures that the preconceived views of subjects and clinicians cannot systematically bias the assessment of

outcomes. Meta analysis of controlled trials shows that the estimates of treatment effects can be exaggerated when there is failure to conceal random allocation and in the absence of double blinding (Sibbald and Roland, 1998).

Stratification is the process of dividing the population of interest into homogeneous sub-populations called strata before sampling. Stratification allows one to make separate inferences for the subpopulations as well as comparing them. In general, stratification improves the precision of estimates of population quantities (Fienberg, 2003).

In this study, gender stratification alone was employed. The experimental and control groups should each have consisted of 8 males and 9 females, but after unblinding the study the experimental group consisted of 7 males and 10 females, while the control group consisted of 9 males and 8 females (due to the effect of dropouts and replacements). Thus, although the proportion of males and females in each group was not according to their stratification in the population, the proportion of males and females in the study as a whole was according to their stratification in the population.

3.1.1 Inclusion criteria

- Male or female;
- Any race;
- The diagnosis of ACNE VULGARIS, i.e. the presence of comedones, papules, pustules and nodular or cystic lesions (BMJ Evidence Centre, 2010). A minimum of 8 non-inflamed and/or inflamed lesions are required. Less than 10 is regarded as mild acne, according to the BMJ Evidence Centre (2010);
- Between the ages of 13 and 35;
- No form of acne treatment (allopathic, homoeopathic or herbal) for at least 4 weeks before entrance to the study Burke and Cunliffe (1984:89);
- English conversant patients as all consultations were conducted in English;

- Resident in the Greater Durban area for easy access to the Durban University of Technology Homoeopathic Day Clinic.

3.1.2 Exclusion criteria

- Acne fulminans, conglobate acne, or acne rosacea;
- Sandpaper acne. The forehead is covered with many, 100 or more, lesions that are superficial and impossible to classify correctly (Burke and Cunliffe, 1984:88);
- Pregnant or lactating females;
- Antibiotic treatment for any reason;
- Dermatological therapy (medicinal or surgical), e.g. treatment for eczema, boils, vitiligo, etc;
- Hormonal therapy, e.g. cortisone, anti-androgens, and oral contraceptives;
- Vitamin and mineral therapy, and Schussler tissue salts.

The researcher advised patients not to change their lifestyle and diet during the period of the study.

3.2 ETHICS

Participants were supplied with an information letter (Appendix B1: English; Appendix B2: Zulu) which explained the purpose and methodology of the study, including the fact that they would be randomly assigned to either an experimental or placebo group. They were informed that they could withdraw at any time. Participants also had to sign an informed consent form (Appendix C1: English; Appendix C2: Zulu), giving the researcher permission to treat them.

All personal information about participants, including the confidential patient information form (Appendix E1: English; Appendix E2: Zulu) were kept strictly private and confidential and will be destroyed after 5 years.

3.3 EVALUATION OF THE RESPONSE TO TREATMENT

3.3.1 Measurement tool

The Leeds counting technique (Burke and Cunliffe, 1984:87-92) (Appendix H) was used to measure the response to treatment, in terms of a reduction in the number of non-inflamed lesions, number of inflamed lesions and total number of acne lesions. Only the face was assessed, as the Leeds counting technique assesses facial lesions only. According to Burke and Cunliffe (1984:87), lesions are divided into the following:

- Non-inflamed lesions (blackheads and whiteheads): Any intermediate lesions are counted according to their major component. Prominent follicles, small milia or trichostasisspinulosa must be excluded as they commonly occur and can badly skew the results.
- Inflamed lesions: These are either superficial or deep.

1. Superficial lesions: These are papules and pustules and vary in size (from 0.1 cm, with minimal erythema to 0.5 cm, with a marked macular flare). The smaller less inflammatory lesions are the less active papules or pustules, while the larger erythematous lesions are the active papules or pustules. About 40% of lesions fall between these two types. However, lesions were assigned according to their major component.
2. Deep lesions: These include nodules, cysts and deep pustules but are mainly nodules (0.5 cm or larger). Palpation is required as some nodules are easily palpable but almost invisible.
3. Macules: Represent the resolving phase of superficial or deep lesions and are either small or large. They contribute to the overall degree of inflammation and therefore should be included in the assessment of acne. They become brown and much less distinct as they evolve. Individual lesion counting may then become very difficult.

A vernier caliper, was used to accurately measure the size of the lesions in order to classify them (Govender, 2003; Nijland, 2005).

3.3.2 Counting of acne lesions

According to Burke and Cunliffe (1984:87), counting of lesions is not easy and perfection takes time. Attention to the following details, according to Burke and Cunliffe (1984:87-88), will help to avoid errors:

- The patient should be sitting comfortably, allowing the observer to move easily around the patient to count each area.
- Good background fluorescent lighting is required. In addition, Burke and Cunliffe (1984) recommend the use of a Brighton 1001 fluorescent lamp which can be easily moved to illuminate both sides of the patient.
- When counting, the face is divided into left and right sides. Both sides are counted. Right-left division is difficult in some patients as lesions are clustered around the midline. The forehead, cheeks and chin are then counted separately and the counts are combined. Lesions from one area only are counted by some authors. As several sites are affected by acne and may improve at one site as it deteriorates at another, it is preferable to count the whole face.
- Palpation is necessary as some macules may resemble a nodule but do not show depth at all on palpation, and a nodule may be hardly visible but on palpation lies deep in the skin.
- Stretching of the skin is not permitted during counting, as stretching increases the number of visible whiteheads and blackheads, but the degree of stretching may vary. For similar reasons, it is recommended that no lens be used. A lesion is not counted if it is impalpable and not obvious with good lighting.

Non-inflamed lesions on or around the edge of the nose are not counted, due to the confusion of the non-inflamed lesions with prominent follicles in these areas (Burke and Cunliffe, 1984:88). The Brighton 1001 fluorescent lamp was not available in Durban. Therefore, a movable fluorescent magnifying lamp was used instead (Radiant Magnifying Lamp T5 Fluorescent AL8066).

3.3.3 Pitfalls for the unwary

Pitfalls for the unwary, according to Burke and Cunliffe (1984:88-89), are:

- Prominent follicles: Non-inflamed lesions can be confused with prominent follicles around the nose and on the chin and this creates a problem especially in mid-teenagers. Therefore, it is recommended that non-inflamed lesions should not be counted either on the nose or around the edge of the nose.
- Sandpaper acne: 2% of teenagers have sandpaper acne. In patients with sandpaper acne, 100 or more very superficial lesions cover the forehead. These are impossible to classify correctly and therefore these patients should be excluded from clinical trials.
- Hair styles: A large number of young people frequently change their hairstyles. Non-inflamed lesions may be masked by long and uncut hair and therefore counting these lesions should be avoided around the hairline. However, recognising inflamed lesions in this area is usually not difficult.
- Shaving: During a clinical trial, a moustache or beard may be grown by patients and this can complicate results. Shaving trauma may also cause a low grade folliculitis on the chin and the neck. Folliculitis associated papules and pustules are felt much less easily than acne lesions. Patients who shave should shave every day, preferably at a constant time, as interpretation of lesions can be affected by stubble.
- Cosmetics: Some females use make-up despite advising them not to. The make-up must be removed and the patient should be observed 30 minutes later, when erythema produced by washing has settled.
- Ultraviolet radiation: Non-inflamed lesions will be camouflaged and inflamed lesions made to look less inflamed by ultraviolet radiation. Therefore, trials should not be conducted during summer (this study took place in winter, April to November 2012).
- Other dermatoses: Sycosis barbae may occur in association with acne and a low grade seborrhoeic eczema may simulate a primary irritant dermatitis

which is commonly seen as a result of treatments such as benzoyl peroxide.

3.4 PREPARATION OF THE HOMOEOPATHIC COMPLEX AND PLACEBO

The homoeopathic complex and placebo were prepared in lactose tablet form by Natura Laboratory (owned by CoMED Health) in Pretoria.

In an e-mail communication on 16 August 2011, the Responsible Homoeopath at Natura Laboratory, Dr Karagiannakis, indicated that the German Homoeopathic Pharmacopoeia does not provide a procedure concerning complex preparations. Therefore an in-house method is used which is the following:

- To get the desired potency of a remedy, the starting substance was that of the same remedy but in a lower potency.
- Each individual ingredient was potentised up from their respective starting potencies (Method 5a of the German Homoeopathic Pharmacopoeia (British Homoeopathic Association, 1985) until they reached an 8CH potency (one potency lower than the final desired 9CH).
- All the individual remedies were then combined to make a homoeopathic complex.
- One part of this combination (homoeopathic complex) was then added to 99 parts of 96% alcohol and then potentised 100 times by hand to get to the desired potency, 9CH.
- The homoeopathic complex was made up in 96% alcohol, this being the standard alcohol percentage used to medicate tablets.
- Tablets were then medicated using 150 drops of the homoeopathic complex per 1000 tablets as a single impregnation technique.
- The placebo tablets were impregnated using 150 drops of the same batch of 96% alcohol used for making up the 9CH complex potency, per 1000 tablets as a single impregnation technique.
- The individual tablets had an average weight of 250 mg.

The starting substances for the homoeopathic complex prepared for this study were:

- *Kalium bromatum* D1 in 20% ethanol.
- *Natrum muriaticum* D2 in 20% ethanol.
- *Selenium* 4CH in 43% ethanol.
- *Sulphur* D6 in 20% ethanol.
- *Thuja occidentalis* mother tincture HAB 3a.

The final homoeopathic complex consisted of the following remedies:

- *Kalium bromatum* 9CH
- *Natrum muriaticum* 9CH
- *Selenium* 9CH
- *Sulphur* 9CH
- *Thuja occidentalis* 9CH

The placebo lactose tablets were impregnated with the same batch of 96% alcohol as was used to make up the final stage of the homeopathic complex. The placebo was indistinguishable from the homoeopathic complex in that all tablets were of the same size, shape and taste. Containers used to hold the complex and placebo tablets were identical in shape and size and had the same labels.

3.5 DISPENSING AND ADMINISTRATION OF THE MEDICINE

The homeopathic complex and placebo tablets were dispensed in 50 ml white plastic containers, by a neutral dispenser according to a randomisation sheet drawn up by the clinic director of the Durban University of Technology Homoeopathic Day Clinic. Each 50 ml container contained 42 tablets which were sufficient for the duration of the study, and was given to the participant after the first consultation.

Participants were instructed to place one tablet under the tongue until the tablet dissolves, daily on waking, for 6 weeks. Each participant was given a sheet which

instructed them on how to take their medication (Appendix I1: English; Appendix I2: Zulu).

3.6 SAFETY OF HOMOEOPATHIC MEDICINE

Currently there is no mechanism in South Africa for registering individual homoeopathic medicines, but they are recorded in the Chiropractors, Homoeopaths and Allied Health Professions Second Amendment Act (Department of Health, 2000) as being the medicines used by homoeopaths to treat their patients.

In this study, participants were informed in the information letter (Appendix B1: English; Appendix B2: Zulu) and child assent form (Appendix D1: English; Appendix D2: Zulu) that there may be a temporary aggravation of their presenting symptoms (i.e. acne) as a result of the medication, but if this occurred it would be transient and would likely be followed by either symptoms settling again to their previous state or an improvement of symptoms (Thompson, Barron and Spence, 2004:204). Specific possible adverse effects were not listed in the information letter because this may have produced negative expectations and therefore negative effects. However, the participants were informed that if any symptoms emerged which made them worried, they should contact the researcher who will contact the supervisor who will make a decision on how to evaluate and deal with those symptoms.

The precise risk-benefit ratio of this study could not be calculated. However, the risk of an adverse event is likely to be lower than if conventional medicine was being used. The ECCH paper (2009:11) quotes a study by Haidvogl et al. (2007) regarding treatment for acute respiratory and ear complaints involving 1 577 patients (857 on homoeopathic treatment) where adverse events occurred more frequently in participants receiving conventional treatment (7.6%), compared to those in the homoeopathic group (3.1%).

3.7 CONSULTATIONS

Each consultation took place at the Homoeopathic Day Clinic at the Durban University of Technology, in the afternoons. Permission to use the clinic for consultations was obtained from the clinic director of the Durban University of Technology Homoeopathic Day Clinic. The duration of the study, for each patient, was 6 weeks which included 3 consultations, i.e. initial consultation followed by 2 consultations at 3 weekly intervals. Entry into the study was completely voluntary and participants could withdraw from the study at any time.

3.7.1 The first consultation

- The researcher met the participant for the first time.
- The participant read the information letter, which was available in English (Appendix B1) and Zulu (Appendix B2).
- The researcher diagnosed whether the participant had acne vulgaris according to the diagnostic criteria of the BMJ Evidence Centre (2010) and ensured that the participant met the inclusion and exclusion criteria. The participant then signed the informed consent form, which was available in English (Appendix C1) and Zulu (Appendix C2). A child assent form, available in English (Appendix D1) and Zulu (Appendix D2), was given to children under 18 years of age. Parents/guardians were required to grant their children permission to participate in the clinical trial and therefore also needed to sign the consent section of the child assent form. Participants then filled in a confidential patient information form, which was available in English (Appendix E1) and Zulu (Appendix E2). This form recorded demographic information.
- The researcher then took a detailed case history (Appendix F) and performed a complete physical examination (Appendix G) (Schultz, 2007).
- The lesions were then counted and assessed according to the Leeds counting technique (Burke and Cunliffe, 1984:87-93). The number of acne lesions was recorded on an assessment sheet (The Leeds counting technique) (Appendix H) (Burke and Cunliffe, 1984:87). Counting was

verified by one of two registered homoeopaths, who were appointed for this purpose.

- The duration of the first consultation was 90 minutes.
- A neutral dispenser dispensed the complex or placebo according to a randomisation sheet drawn up by the clinic director of the Durban University of Technology Homoeopathic Day Clinic.

3.7.2 The second consultation

- The second consultation occurred 3 weeks after the first consultation.
- The participant was required to bring the tablet container to the consultation in order for the researcher to count the number of tablets. This was to ensure that the participant was compliant with taking his or her medication.
- The participant's case was reviewed and the researcher asked about any reaction to the treatment. The participant's vital signs (blood pressure, pulse rate, respiratory rate, temperature, height and weight) were checked.
- The lesions were then counted again and assessed according to the Leeds counting technique (Burke and Cunliffe, 1984:87-93). The number of acne lesions was recorded on an assessment sheet (The Leeds counting technique) (Appendix H) (Burke and Cunliffe, 1984:87). Counting was verified by one of two registered homoeopaths, who were appointed for this purpose.
- The duration of the second consultation was an hour.

3.7.3 The third consultation

- The third consultation happened 3 weeks after the second consultation.
- The participant was required to bring the tablet container to the consultation in order for the researcher to count the number of tablets. This was to ensure that the participant was compliant with taking his or her medication.

- The participant's case was reviewed and the researcher asked about any reaction to the treatment. The participant's vital signs (blood pressure, pulse rate, respiratory rate, temperature, height and weight) were checked.
- The lesions were then counted again and assessed according to the Leeds counting technique (Burke and Cunliffe, 1984:87-93). The number of acne lesions was recorded on their assessment sheet (The Leeds counting technique) (Appendix H) (Burke and Cunliffe, 1984:87). Counting was verified by one of two registered homoeopaths, who were appointed for this purpose.
- The duration of the third consultation was an hour.
- The participant was thanked for participating in the research.

The parent/guardian was required to be present at each consultation, including the examination and measurement, with his/her child. Female participants who reported to the consultations with applied makeup were asked to wash their faces, and their acne lesions were counted at least 30 minutes later to allow the erythema resulting from washing to settle (Burke and Cunliffe, 1984:88). All equipment, including the stethoscope, ophthalmoscope, blood pressure meter, thermometer, vernier caliper and the fluorescent magnifying lamp were thoroughly cleaned with alcohol swabs before and after each consultation. This was to ensure that equipment were clean and suitable to use during examination and measurement.

After completion of the study, the randomisation sheet was unblinded. Participants who were identified as having been in the placebo group were notified and invited to come and collect a free course of the experimental homoeopathic complex.

3.8 DATA COLLECTION AND STATISTICS

3.8.1 Data collection

The data of this study was the number of non-inflamed, number of inflamed and total number of acne lesions (number of non-inflamed and inflamed lesions combined), present at each consultation. This was recorded on an assessment sheet (The Leeds counting technique, Appendix H) (Burke and Cunliffe, 1984:87) at each consultation for each participant. After all the data were collected, the randomisation sheet was unblinded and participants were identified as having been in the experimental (homoeopathic acne complex) or control (placebo) group. The researcher then transferred the data, i.e. the number of non-inflamed and number of inflamed lesions for each participant recorded at each consultation, from the assessment sheet to an Excel spreadsheet as two separate groups (experimental and control), and this was sent for statistical analysis. Appendix J shows raw data of the study and the age and race of every participant.

3.8.2 Statistical analysis

SPSS version 20 (IBM Corp, 2011) was used for data analysis. The median number of lesions per group were evaluated over time and compared between the groups using the Mann-Whitney U test, and compared within groups using the Friedman test. Line graphs showing the change in the number of lesions over time were shown by treatment or control group. A p value <0.05 was considered as statistically significant.

3.8.2.1 The Friedman Test

The Friedman test is a non-parametric test. It is also a distribution free test. No assumptions about data distribution are made. This test is used to compare more than two paired groups (biostatistician T. Esterhuizen, personal communication 20 November 2012).

According to MacFarland (1998), the Friedman Two way analysis of variance is useful in the following cases:

1) to know if there are differences present between three or more samples and
2) when data are ordinal (ranked).

There are numerous times, when only the use of ordinal data is possible. In this case the Friedman test may be appropriate, when there are multiple analyses and a possible interaction (MacFarland, 1998).

3.8.2.2 The Mann-Whitney U Test

This is a non-parametric test. It can be used in place of an unpaired t-test. The Mann-Whitney U test is used to test the null hypothesis that two samples come from the same population, that is, they have the same median, or alternatively whether observations in one sample tend to be larger than observations in the other. Despite being a non-parametric test, the Mann-Whitney U test does assume that the two distributions are similar in shape (Shier, 2004).

The Mann-Whitney U test is the non-parametric equivalent to the independent samples t-test. Medians of two independent groups are compared using this test (biostatistician T. Esterhuizen, personal communication 26 March 2012).

Both the Mann-Whitney U Test and the Friedman test use the ranks of the data rather than actual values. This ensures that in cases where the data are skewed, no assumptions of distribution are used and thus an unbiased comparison of medians is ensured (biostatistician T. Esterhuizen, personal communication 26 March 2012).

3.8.2.3 Procedures

3.8.2.3.1 Procedure 1 (intra-group analysis)

The change in the number of non-inflamed, number of inflamed and total number of acne lesions (number of non-inflamed and inflamed lesions combined) was compared between consultations within the experimental (complex) group and within the control (placebo) group using the Friedman test ($p < 0.05$).

3.8.2.3.2 Procedure 2 (inter-group analysis)

The change in the number of non-inflamed, number of inflamed and total number of acne lesions (number of non-inflamed and inflamed lesions combined) between baseline and the end of the study was compared between the experimental (complex) group and control (placebo) group using the Mann-Whitney U test.

Null hypothesis = H_0 = The homoeopathic complex is not effective in the treatment of acne vulgaris.
Alternative hypothesis = H_1 = The homoeopathic complex is effective in the treatment of acne vulgaris.

If $p > 0.05$, there is no significant difference in the number of non-inflamed, number of inflamed and total number of acne lesions between groups. As a result, the null hypothesis is retained.

If $p < 0.05$, there is a significant difference in the number of non-inflamed, number of inflamed and total number of acne lesions between groups. As a result, the null hypothesis is rejected.

CHAPTER 4
RESULTS

4.1 INTRODUCTION

This chapter states the results of this study, i.e. it contains the analysis of the objective data (non-inflamed, inflamed and total acne lesions). The data of this study was the physical, objective acne lesions. The demographics (age, race, gender) will also be explained briefly, but to determine the efficacy of the homoeopathic complex, the statistical analysis of the physical acne lesions was the main focus. Therefore the data of this study was the number of acne lesions per type of lesion.

The researcher made sure that participants fulfilled the inclusion and exclusion criteria before participating in the study. In addition, the researcher diagnosed the participants as having acne vulgaris according to diagnostic criteria of the BMJ Evidence Centre (2010). Participants were randomly assigned to an experimental (homoeopathic complex) group or a control (placebo) group, according to gender stratification. Initially, the experimental and control groups were each supposed to consist of 8 males and 9 females, but after unblinding the experimental group consisted of 7 males and 10 females while the control group consisted of 9 males and 8 females, due to dropouts. The case history (Appendix F), physical examination (Appendix G) (Schultz, 2007), counting and recording of the number of acne lesions were performed by the researcher. Counting was verified by one of two qualified and registered homoeopaths appointed for this purpose. The number of acne lesions were counted and assessed according to the Leeds counting technique (Burke and Cunliffe, 1984:87-93). The number of non-inflamed and number of inflamed lesions was recorded on an assessment sheet (Appendix H) (Burke and Cunliffe, 1984:87), for each participant at each of the 3 consultations, i.e. an initial consultation followed by 2 follow-up consultations at 3 weekly intervals, over a treatment period of 6 weeks. Patient assessment and data collection took place at the Durban University of Technology Homoeopathic

Day Clinic on weekday afternoons. Appendix J shows the raw data of the study (number of non-inflamed, number of inflamed and the total number of acne lesions), including demographic information such as age and race of every participant.

SPSS version 20 (IBM Corp, 2011) was used to analyse the data. A p value of < 0.05 was considered as statistically significant. The number of lesions was found to have a non-normal distribution and thus was compared between the three time points within groups using non-parametric paired Friedman tests. The change in the number of lesions was calculated by subtracting the number at baseline from the number at the end of the trial in each individual. The median change was compared between groups using non-parametric Mann-Whitney U tests for two independent groups.

Intra-group analysis and intergroup analysis of lesions were performed for males and females separately and also performed without considering gender of the participants. The experimental group is the homoeopathic acne complex group (or simply, the complex group) and the control group is the placebo group.

4.2 DEMOGRAPHICS

4.2.1 Age

Table 1: Age distribution within the experimental (complex) and control (placebo) groups.

Group Statistics						P value
	group	N	Mean	Std. Deviation	Std. Error Mean	
age	Experimental group	17	22.0588	3.32548	.80655	0.905
	Placebo group	17	21.9412	2.30409	.55882	

As can be seen from Table 1, the youngest participant in this study was 18 years of age and the oldest participant was 31 years of age. The following are the number of participants from the various age groups that participated in the study: 18 years – 1 participant, 19 years – 4 participants, 20 years – 7 participants, 21 – 7 participants, 22 – 2 participants, 23 – 6 participants, 24 – 1 participant, 25 – 2

participants, 26 – 1 participant, 27 – 2 participants and 31 – 1 participant. The majority of participants were 19 to 23 years of age (teen to early adulthood). There was no significant difference between the two groups with respect to age (p = 0.905).

4.2.2 Race

Table 2: Race distribution within the experimental (complex) and control (placebo) groups.

			race			Total
			BLACK	INDIAN	WHITE	
group	Experimental group	Count	13	3	1	17
		% within group	76.5%	17.6%	5.9%	100.0%
	Placebo group	Count	14	3	0	17
		% within group	82.4%	17.6%	0.0%	100.0%
Total		Count	27	6	1	34
		% within group	79.4%	17.6%	2.9%	100.0%

Table 2 shows that there was no significant difference between the two groups with respect to race (p = 0.595).

4.2.3 Gender

Table 3: Gender distribution within the experimental (complex) and control (placebo) groups.

			gender		Total
			Male	Female	
group	Experimental group	Count	7	10	17
		% within group	41.2%	58.8%	100.0%
	Placebo group	Count	9	8	17
		% within group	52.9%	47.1%	100.0%
Total		Count	16	18	34
		% within group	47.1%	52.9%	100.0%

The experimental (complex) group consisted of 7 males and 10 females while the control (placebo) group consisted of 9 males and 8 females. As can be seen from Table 3, there was no significant difference between the two groups with respect to gender (p = 0.492).

4.3 PROCEDURE 1 (INTRA-GROUP ANALYSIS)

4.3.1 Statistical analysis involving gender classification

4.3.1.1 Non-inflamed lesions

4.3.1.1.1 Males: complex group

Table 4: Rate of change in the number of non-inflamed lesions between consultations for males in the experimental (complex) group.

Statistics[a]

		Non-inflamed 1	Non-inflamed 2	Non-inflamed 3
N	Valid	7	7	7
	Missing	0	0	0
Minimum		22	17	13
Maximum		77	83	54
Percentiles	25	27.00	30.00	17.00
	50	64.00	43.00	35.00
	75	67.00	59.00	44.00

a. gender = Male, group = Experimental group

Table 4 shows that there was a significant reduction in the number of non-inflamed lesions in males in the complex group ($p = 0.004$), i.e. there was a significant difference in the number of non-inflamed lesions between consultations in males within the complex group.

4.3.1.1.2 Males: placebo group

Table 5: Rate of change in the number of non-inflamed lesions between consultations for males in the control (placebo) group.

Statistics[a]

		Non-inflamed 1	Non-inflamed 2	Non-inflamed 3
N	Valid	9	9	9
	Missing	0	0	0
Minimum		25	18	19
Maximum		96	66	55
Percentiles	25	31.00	24.50	21.50
	50	41.00	35.00	32.00
	75	74.00	53.00	45.00

a. gender = Male, group = Placebo group

Table 5 shows that there was a significant reduction in the number of non-inflamed lesions in males in the placebo group (p = 0.001), i.e. there was a significant difference in the number of non-inflamed lesions between consultations in males within the placebo group.

4.3.1.1.3 Females: complex group

Table 6: Rate of change in the number of non-inflamed lesions between consultations for females in the experimental (complex) group.

Statistics[a]

		Non-inflamed 1	Non-inflamed 2	Non-inflamed 3
N	Valid	10	10	10
	Missing	0	0	0
Minimum		19	21	17
Maximum		86	91	102
Percentiles	25	27.75	27.75	25.75
	50	56.50	48.00	35.50
	75	80.25	64.00	48.50

a. gender = Female, group = Experimental group

Table 6 shows that there was no significant change in the number of non-inflamed lesions in females in the complex group (p = 0.387), i.e. there was no

significant difference in the number of non-inflamed lesions between consultations in females within the complex group.

4.3.1.1.4 Females: placebo group

Table 7: Rate of change in the number of non-inflamed lesions between consultations for females in the control (placebo) group.

Statistics[a]

		Non-inflamed 1	Non-inflamed 2	Non-inflamed 3
N	Valid	8	8	8
	Missing	0	0	0
Minimum		37	22	26
Maximum		181	112	116
Percentiles	25	68.00	37.75	35.50
	50	92.00	64.50	49.00
	75	138.00	98.00	93.25

a. gender = Female, group = Placebo group

Table 7 shows that there was a significant reduction in the number of non-inflamed lesions in females in the placebo group ($p = 0.002$), i.e. there was a significant difference in the number of non-inflamed lesions between consultations in females within the placebo group.

4.3.1.2 Inflamed lesions

4.3.1.2.1 Males: complex group

Table 8: Rate of change in the number of inflamed lesions between consultations for males in the experimental (complex) group.

Statistics[a]

		Inflamed 1	Inflamed 2	Inflamed 3
N	Valid	7	7	7
	Missing	0	0	0
Minimum		40	33	21
Maximum		91	83	83
Percentiles	25	46.00	44.00	38.00
	50	54.00	59.00	50.00
	75	75.00	78.00	81.00

a. gender = Male, group = Experimental group

Table 8 shows that there was no significant change over time in the number of inflamed lesions in males in the complex group ($p = 0.772$), i.e. there was no significant difference in the number of non-inflamed lesions between consultations in males within the complex group.

4.3.1.2.2 Males: placebo group

Table 9: Rate of change in the number of inflamed lesions between consultations for males in the control (placebo) group.

Statistics[a]

		Inflamed 1	Inflamed 2	Inflamed 3
N	Valid	9	9	9
	Missing	0	0	0
Minimum		29	27	25
Maximum		149	86	92
Percentiles	25	41.00	38.00	35.00
	50	60.00	56.00	55.00
	75	75.50	73.50	64.00

a. gender = Male, group = Placebo group

Table 9 shows that there was no significant change over time in the number of inflamed lesions in males in the placebo group (p = 0.169), i.e. there was no significant difference in the number of inflamed lesions in males within the placebo group.

4.3.1.2.3 Females: complex group

Table 10: Rate of change in the number of inflamed lesions between consultations for females in the experimental (complex) group.

Statistics[a]

		Inflamed 1	Inflamed 2	Inflamed 3
N	Valid	10	10	10
	Missing	0	0	0
Minimum		23	20	19
Maximum		84	105	79
Percentiles	25	47.00	42.25	25.75
	50	64.50	61.50	52.00
	75	81.50	71.00	58.00

a. gender = Female, group = Experimental group

Table 10 shows that there was a significant reduction over time in the number of inflamed lesions in females in the complex group (p = 0.002), i.e. there was a significant difference in the number of inflamed lesions between consultations in females within the complex group.

4.3.1.2.4 Females: placebo group

Table 11: Rate of change in the number of inflamed lesions between consultations for females in the control (placebo) group.

Statistics[a]

		Inflamed 1	Inflamed 2	Inflamed 3
N	Valid	8	8	8
	Missing	0	0	0
Minimum		46	38	38
Maximum		235	141	139
Percentiles	25	51.75	39.25	43.25
	50	74.50	46.50	48.00
	75	142.75	98.25	83.25

a. gender = Female, group = Placebo group

Table 11 shows that there was a significant reduction over time in the number of inflamed lesions in females in the placebo group ($p = 0.010$), i.e. there was a significant difference in the number of inflamed lesions between consultations in females within the placebo group.

4.3.1.3 Total acne lesions

The number of non-inflamed and inflamed lesions was added together at each time point.

4.3.1.3.1 Males: complex group

Table 12: Rate of change in the total number of acne lesions between consultations for males in the experimental (complex) group.

Statistics[a]

		total1	total2	total3
N	Valid	7	7	7
	Missing	0	0	0
Minimum		62.00	50.00	34.00
Maximum		168.00	144.00	125.00
Percentiles	25	80.0000	87.0000	66.0000
	50	112.0000	94.0000	102.0000
	75	142.0000	142.0000	117.0000

a. group = Intervention, gender = Male

Table 12 shows that there was a statistically significant reduction in the total number of acne lesions in males in the complex group (p = 0.019), i.e. there was a significant difference in the total number of acne lesions in males within complex group.

4.3.1.3.2 Males: placebo group

Table 13: Rate of change in the total number of acne lesions between consultations for males in the control (placebo) group.

Statistics[a]

		total1	total2	total3
N	Valid	9	9	9
	Missing	0	0	0
Minimum		54.00	45.00	45.00
Maximum		245.00	147.00	147.00
Percentiles	25	77.0000	70.5000	59.5000
	50	94.0000	81.0000	87.0000
	75	149.5000	129.0000	106.0000

a. group = Placebo, gender = Male

Table 13 shows that there was a statistically significant reduction in the total number of acne lesions in males in the placebo group (p = 0.003), i.e. there was

a significant difference in the total number of acne lesions in males within placebo group.

4.3.1.3.3 Females: complex group

Table 14: Rate of change in the total number of acne lesions between consultations for females in the experimental (complex) group.

Statistics[a]

		total1	total2	total3
N	Valid	10	10	10
	Missing	0	0	0
Minimum		42.00	41.00	41.00
Maximum		167.00	196.00	172.00
Percentiles	25	74.7500	67.5000	58.5000
	50	132.5000	107.0000	83.5000
	75	157.0000	133.5000	107.2500

a. group = Intervention, gender = Female

Table 14 shows that there was a statistically significant reduction in the total number of acne lesions in females in the complex group ($p = 0.001$), i.e. there was a significant difference in the total number of acne lesions between consultations in females in the complex group.

4.3.1.3.4 Females: placebo group

Table 15: Rate of change in the total number of acne lesions between consultations for females in the control (placebo) group.

Statistics[a]

		total1	total2	total3
N	Valid	8	8	8
	Missing	0	0	0
Minimum		86.00	61.00	64.00
Maximum		416.00	248.00	244.00
Percentiles	25	120.2500	78.7500	82.7500
	50	161.5000	110.0000	96.5000
	75	280.5000	200.0000	184.0000

a. group = Placebo, gender = Female

Table 15 shows that there was a statistically significant reduction in the total number of acne lesions in females in the placebo group (p = 0.002), i.e. there was a significant difference in the total number of acne lesions between consultations in females within the placebo group.

4.3.2 Statistical analysis without gender classification

4.3.2.1 Non-inflamed lesions

Table 16: Rate of change in the number of non-inflamed lesions between consultations within the experimental (complex) group and within the control (placebo) group.

Report

group		Non-inflamed 1	Non-inflamed 2	Non-inflamed 3
Experimental group	Median	58.00	47.00	35.00
	Minimum	19	17	13
	Maximum	86	91	102
Placebo group	Median	68.00	45.00	36.00
	Minimum	25	18	19
	Maximum	181	112	116
Total	Median	64.50	45.50	35.50
	Minimum	19	17	13
	Maximum	181	112	116

Table 16 shows that there was a statistically significant reduction in the number of non-inflamed lesions in the complex group (p = 0.006), i.e. there was a significant difference in the number of non-inflamed lesions within the complex group.

There was a statistically significant reduction in the number of non-inflamed lesions in the placebo group (p < 0.001), i.e. there was a significant difference in the number of non-inflamed lesions within the placebo group.

4.3.2.2 Inflamed lesions

Table 17: Rate of change in the number of inflamed lesions between consultations within the experimental (complex) group and within the control (placebo) group.

Report

group		Inflamed 1	Inflamed 2	Inflamed 3
Experimental group	Median	60.00	61.00	52.00
	Minimum	23	20	19
	Maximum	91	105	83
Placebo group	Median	67.00	51.00	51.00
	Minimum	29	27	25
	Maximum	235	141	139
Total	Median	63.00	57.50	51.50
	Minimum	23	20	19
	Maximum	235	141	139

Table 17 shows that there was a statistically significant reduction in the number of inflamed lesions in the complex group ($p = 0.006$), i.e. there was a significant difference in the number of inflamed lesions between consultations within the complex group.

There was a statistically significant reduction in the number of inflamed lesions in the placebo group ($p = 0.003$), i.e. there was a significant difference in the number of inflamed lesions between consultations within the placebo group.

4.3.2.3 Total acne lesions

Table 18: Rate of change in the total number of acne lesions between consultations within the experimental (complex) group and within the control (placebo) group.

Report

group		total1	total2	total3
Experimental group	Median	118.0000	106.0000	88.0000
	Minimum	42.00	41.00	34.00
	Maximum	168.00	196.00	172.00
Placebo group	Median	147.0000	90.0000	91.0000
	Minimum	54.00	45.00	45.00
	Maximum	416.00	248.00	244.00
Total	Median	122.5000	104.5000	89.5000
	Minimum	42.00	41.00	34.00
	Maximum	416.00	248.00	244.00

Table 18 shows that there was a statistically significant reduction in the total number of acne lesions in the complex group ($p < 0.001$), i.e. there was a significant difference in the total number of acne lesions between consultations within the complex group.

There was a statistically significant reduction in the total number of acne lesions in the placebo group ($p < 0.001$), i.e. there was a significant difference in the total number of acne lesions between consultations within the placebo group.

4.4 PROCEDURE 2 (INTER-GROUP ANALYSIS)

4.4.1 Statistical analysis involving gender classification

4.4.1.1 Non-inflamed lesions

4.4.1.1.1 Males

Table 19: Change in the number of non-inflamed lesions between experimental (complex) and control (placebo) groups in males.

Report[a]

Change in non-inflamed lesions

group	Median	Minimum	Maximum
Experimental group	-12.0000	-33.00	-3.00
Placebo group	-10.0000	-41.00	-5.00
Total	-11.0000	-41.00	-3.00

a. gender = Male

As can be seen from Tables 19 and 20 there was no difference between the complex and placebo groups in terms of the change in the number of non-inflamed lesions in males. Both groups had a similar median reduction (p = 1.000). Therefore, the null hypothesis is retained. Figure 1 shows the equivalence of the rate of change between the groups over time.

Table 20: Hypothesis test summary. The p value for inter-group comparison of the number of non-inflamed lesions in males.

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of Change in non-inflamed lesions is the same across categories of group.	Independent-Samples Mann-Whitney U Test	1.000[1]	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

[1]Exact significance is displayed for this test.

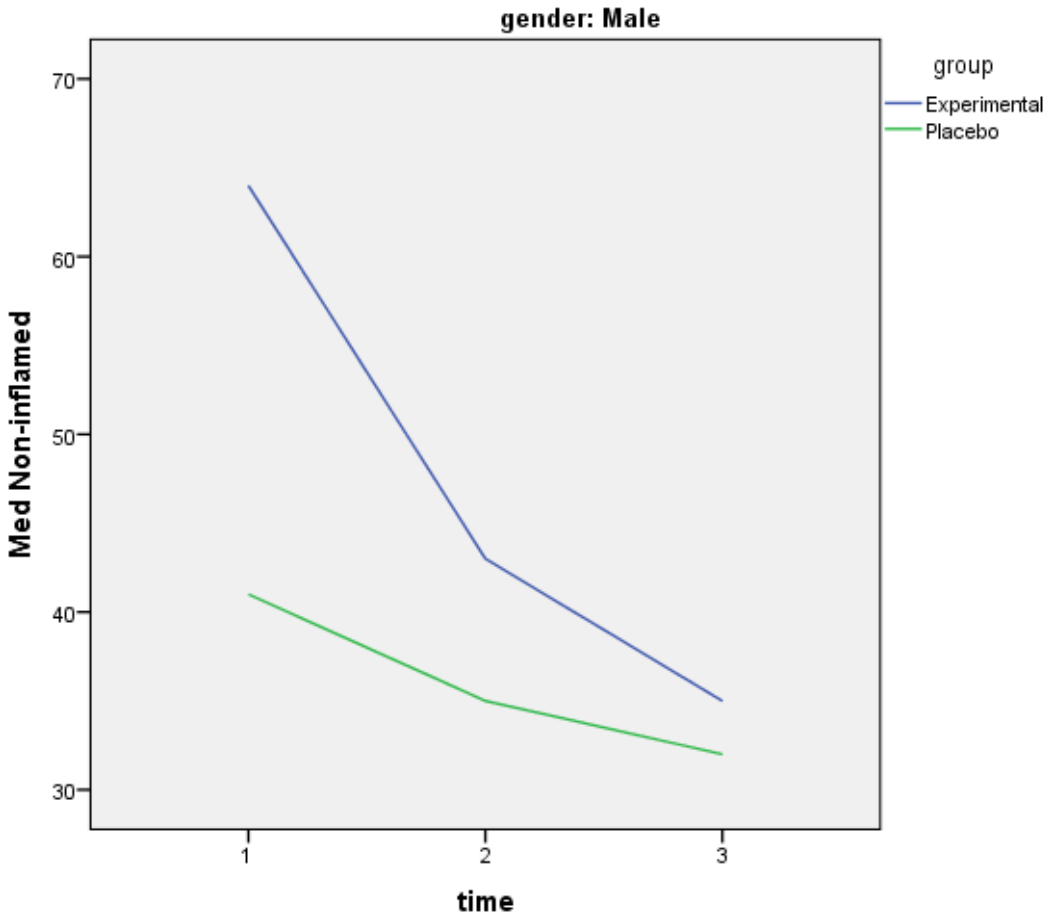

Figure 2: Equivalence of the rate of change in the median number of non-inflamed lesions in males in the experimental (complex) and control (placebo) groups over time.

4.4.1.1.2 Females

Table 21: Change in the number of non-inflamed lesions between experimental (complex) and control (placebo) group in females.

Report[a]

Change in non-inflamed lesions

group	Median	Minimum	Maximum
Experimental group	-17.5000	-46.00	23.00
Placebo group	-42.5000	-76.00	-11.00
Total	-31.5000	-76.00	23.00

a. gender = Female

As can be seen from Table 21 and 22, there was a marginally non-significant difference between the complex and placebo groups in terms of the change in non-inflamed lesions in females (p = 0.055). The trend showed that the placebo

group experiences a higher mean reduction than the complex group. Therefore the null hypothesis is retained. Figure 2 shows the equivalence of the rate of change between the groups over time.

Table 22: Hypothesis test summary. The p value for the inter-group comparison of the number of non-inflamed lesions in females.

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of Change in non-inflamed lesions is the same across categories of group.	Independent-Samples Mann-Whitney U Test	.055[1]	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

[1]Exact significance is displayed for this test.

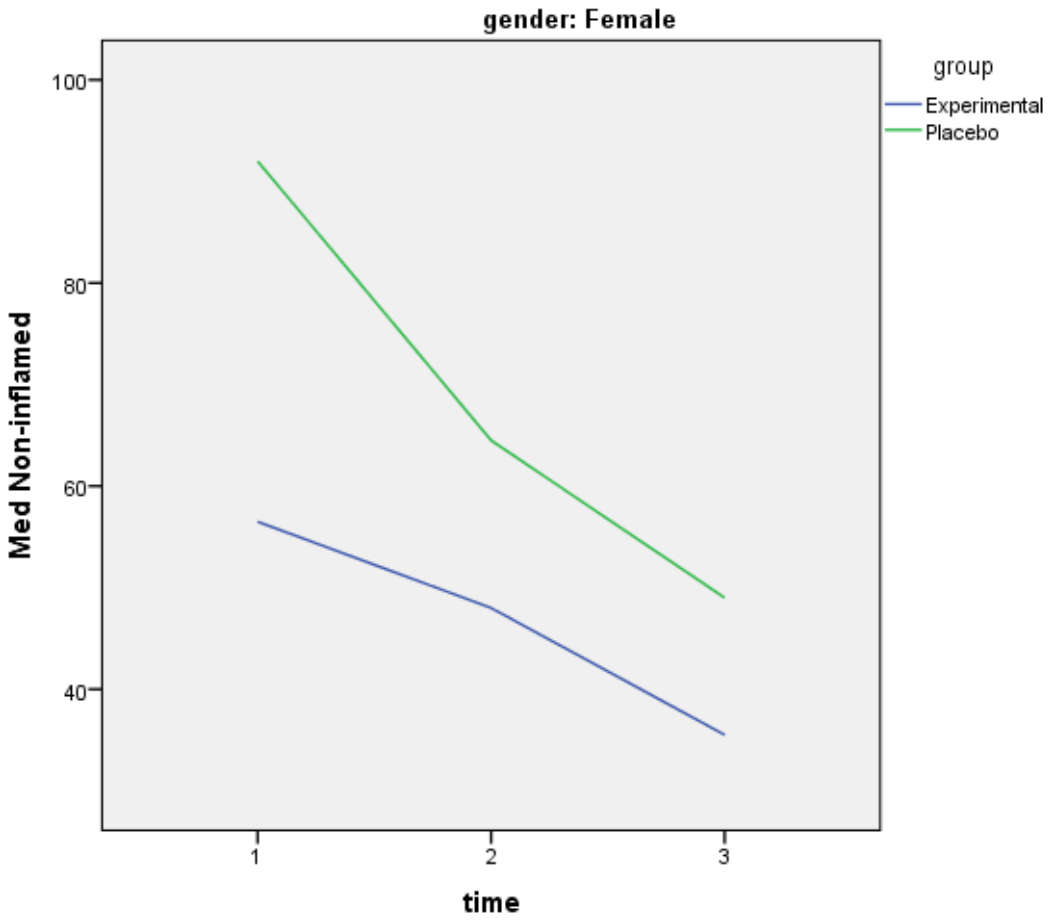

Figure 3: Equivalence of the rate of change in the median number of non-inflamed lesions in females in the experimental (complex) and control (placebo) groups over time

4.4.1.2 Inflamed lesions

4.4.1.2.1 Males

Table 23: Change in the number of inflamed lesions between the experimental (complex) and control (placebo) group in males.

Report[a]

Change in inflamed lesions

group	Median	Minimum	Maximum
Experimental group	-4.0000	-19.00	8.00
Placebo group	-10.0000	-57.00	6.00
Total	-7.0000	-57.00	8.00

a. gender = Male

As can be seen from Table 23 and 24, there was no significant difference between the complex and placebo groups in terms of the change in inflamed lesions in males (p = 0.606). The placebo group showed a slightly higher median reduction than the complex group. Therefore, the null hypothesis is retained. Figure 3 shows the equivalence of the rate of change between the groups over time.

Table 24: Hypothesis test summary. The p value for the inter-group comparison of the number of inflamed lesions in males.

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of Change in inflamed lesions is the same across categories of group.	Independent-Samples Mann-Whitney U Test	.606[1]	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

[1]Exact significance is displayed for this test.

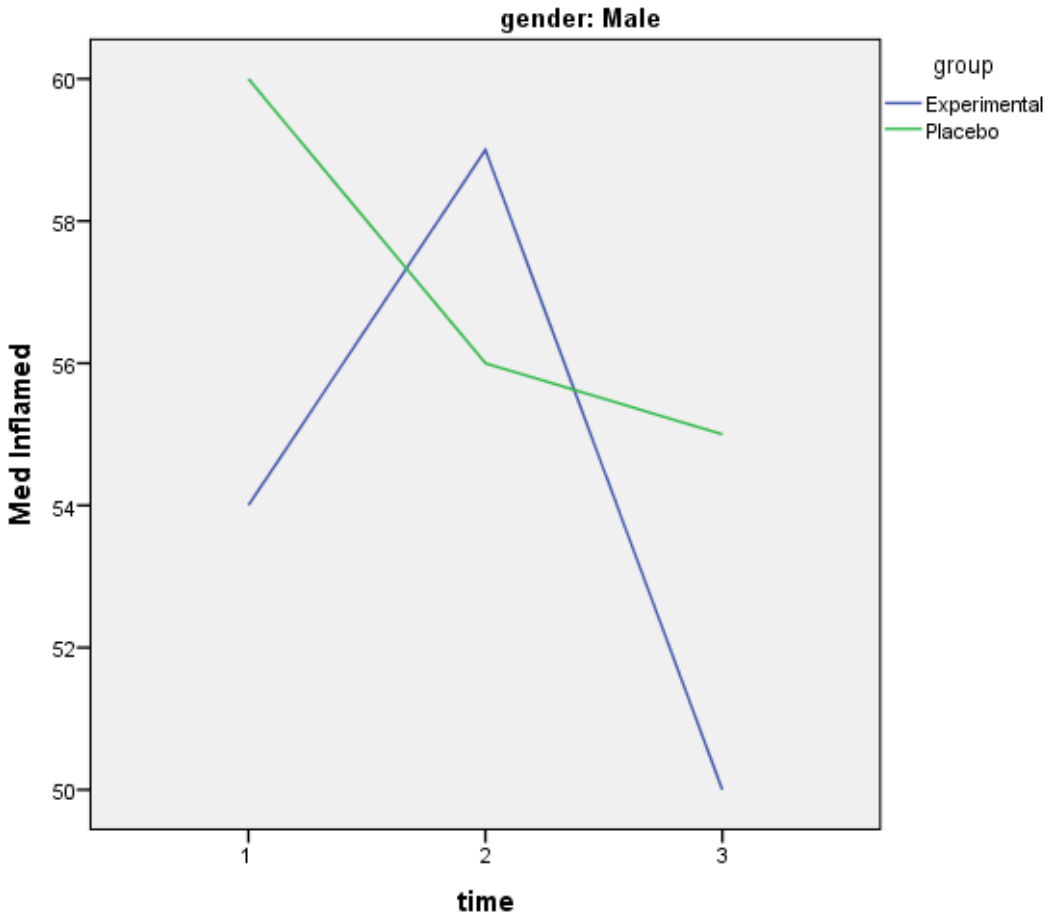

Figure 4: Equivalence of the rate of change in the median number of inflamed lesions in males in the experimental (complex) and control (placebo) groups over time.

4.4.1.2.2 Females

Table 25: Change in the number of inflamed lesions between the experimental (complex) and control (placebo) group in females.

Report[a]

Change in inflamed lesions

group	Median	Minimum	Maximum
Experimental group	-13.5000	-32.00	10.00
Placebo group	-25.5000	-96.00	2.00
Total	-17.0000	-96.00	10.00

a. gender = Female

As can be seen from Tables 25 and 26, there was no significant difference between the complex and placebo groups in terms of the change in the inflamed lesions in females (p = 0.146). The placebo group had a slightly higher median

reduction than the complex group. Therefore, the null hypothesis is retained. Figure 4 shows the equivalence of the rate of change between the groups over time.

Table 26: Hypothesis test summary. The p value for the inter-group comparison of the number of inflamed lesions in females.

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of Change in inflamed lesions is the same across categories of group.	Independent-Samples Mann-Whitney U Test	.146[1]	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

[1]Exact significance is displayed for this test.

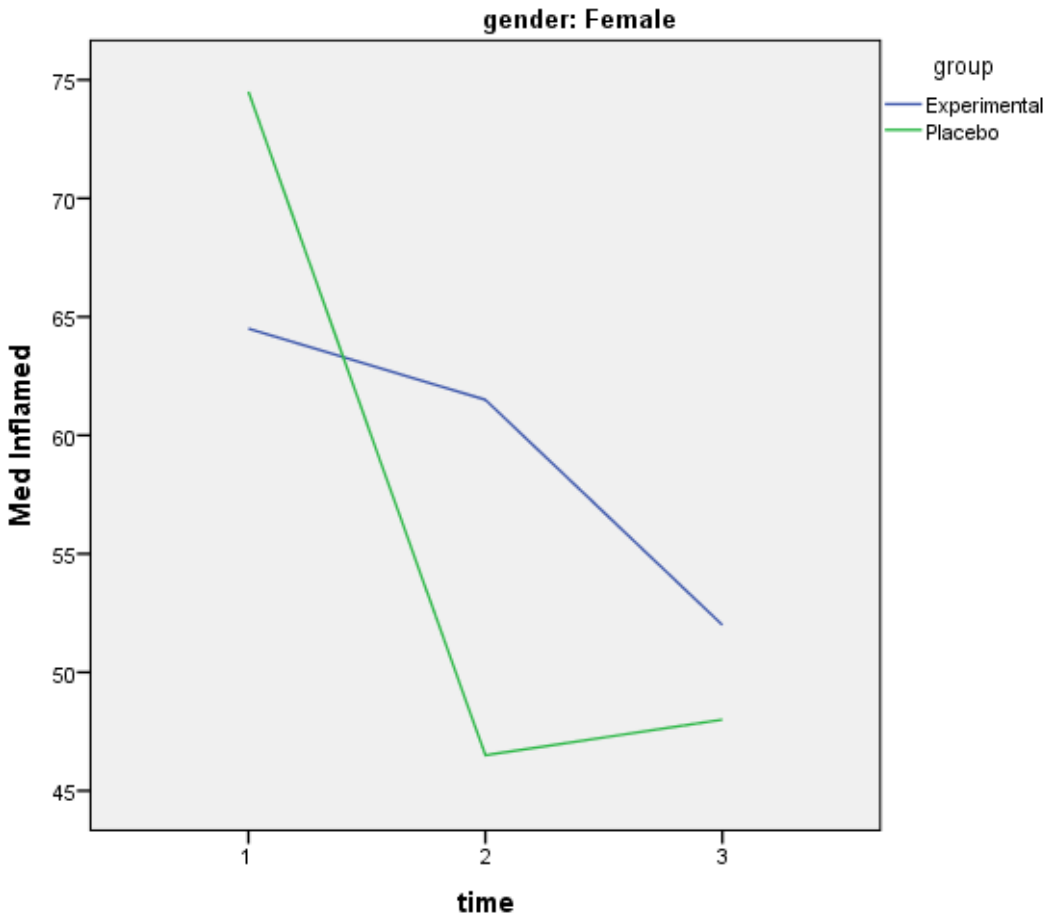

Figure 5: Equivalence of the rate of change in the median number of inflamed lesions in females in the experimental (complex) and control (placebo) groups over time.

4.4.1.3 Total acne lesions

The change in total acne lesions between the first and third time points were compared between the experimental and control groups.

4.4.1.3.1 Males

Table 27: Change in the total number of acne lesions between the experimental (complex) and control (placebo) group in males.

Report[a]

Change in total lesions

group	Median	Minimum	Maximum
Experimental group	-25.0000	-43.00	-2.00
Placebo group	-21.0000	-98.00	-4.00
Total	-22.0000	-98.00	-2.00

a. gender = Male

As can be seen from Tables 27 and 28, in males there was no significant difference in the reduction in total acne lesions between the experimental (complex) and control (placebo) groups (p = 1.000). The complex group showed a slightly higher reduction on average than the placebo group. Therefore, the null hypothesis is retained.

Table 28: Hypothesis test summary. The p value for the inter-group comparison of the total number of acne lesions in males.

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of Change in total lesions is the same across categories of group.	Independent-Samples Mann-Whitney U Test	1.000[1]	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

[1]Exact significance is displayed for this test.

The equivalence of the rate of change in the two groups over time can be seen in the parallel lines of the two groups in the plot below (Figure 5).

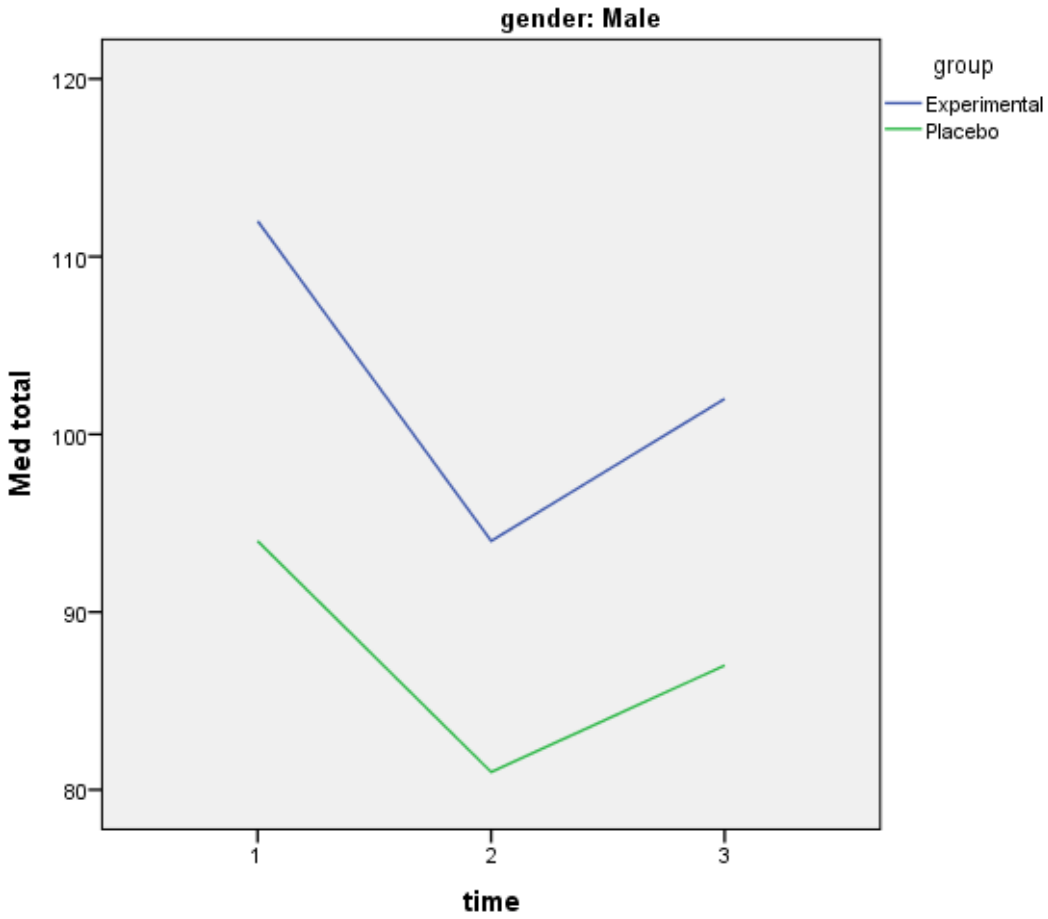

Figure 6: Equivalence of the rate of change in the median total number of acne lesions in males in the experimental (complex) and control (placebo) groups over time.

4.4.1.3.2 Females

Table 29: Change in the total number of acne lesions between the experimental (complex) and control (placebo) group in females.

Report[a]

Change in total lesions

group	Median	Minimum	Maximum
Experimental group	-39.5000	-64.00	33.00
Placebo group	-72.0000	-172.00	-13.00
Total	-49.0000	-172.00	33.00

a. gender = Female

As can be seen in Tables 29 and 30, in females, the experimental (complex) group showed an average reduction of 39.5 lesions and the placebo group

decreased by 72 lesions. This was statistically significant (p = 0.034), meaning that the decrease in total acne lesions was greater in the placebo group than the experimental group. Since the alternative hypothesis in this case was that the reduction in the experimental group is greater than in the control group, the null hypothesis is retained. The conclusion is that there was no effect of the homoeopathic acne complex (intervention) in females in terms of reduction in total number of acne lesions. Figure 6 shows the equivalence of the rate of change between the groups over time.

Table 30: Hypothesis test summary. The p value for the inter-group comparison of the total number of acne lesions in females.

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of Change in total lesions is the same across categories of group.	Independent-Samples Mann-Whitney U Test	.034[1]	Reject the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

[1]Exact significance is displayed for this test.

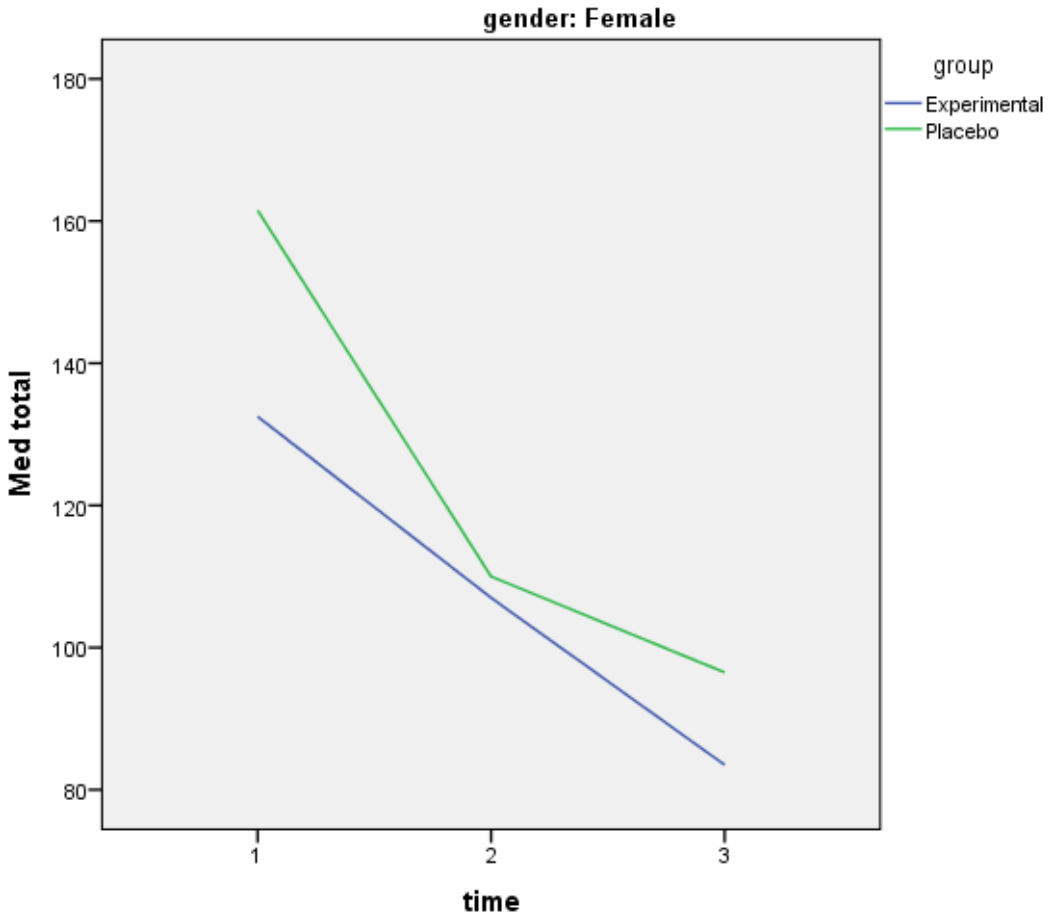

Figure 7: Equivalence of the rate of change in the median total number of acne lesions in females in the experimental (complex) and control (placebo) groups over time.

4.4.2 Statistical analysis without gender classification

4.4.2.1 Non-inflamed, inflamed and total acne lesions

Table 31: Change in the number of non-inflamed, number of inflamed and total number of acne lesions between the experimental (complex) and control (placebo) groups.

Report

group		Change in inflamed lesions	Change in non-inflamed lesions	Change in total lesions
Experimental group	Median	-10.0000	-16.0000	-28.0000
	Minimum	-32.00	-46.00	-64.00
	Maximum	10.00	23.00	33.00
Placebo group	Median	-12.0000	-26.0000	-36.0000
	Minimum	-96.00	-76.00	-172.00
	Maximum	6.00	-5.00	-4.00
Total	Median	-10.5000	-17.5000	-31.5000
	Minimum	-96.00	-76.00	-172.00
	Maximum	10.00	23.00	33.00

Tables 31 and 32 show that there was no significant difference in the number of non-inflamed lesions between the complex and placebo groups ($p = 0.193$). Both groups showed a similar reduction when compared to each other. Therefore, the null hypothesis is retained.

Tables 31 and 32 also show that there was no significant difference in the number of inflamed lesions between the complex and placebo groups ($p = 0.290$). Both groups showed a similar reduction when compared to each other. Therefore, the null hypothesis is retained.

Further, Tables 31 and 32 show there was no significant difference in the total number of acne lesions between the complex and placebo groups ($p = 0.193$). Both groups showed a similar reduction when compared to each other. Therefore, the null hypothesis is retained.

Figures 7-9 show the equivalent rate of change between the groups in the types of lesions and total lesions.

Table 32: Hypothesis test summary. The p value for inter-group comparisons of the number of non-inflamed, number of inflamed and total number of acne lesions.

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of Change in inflamed lesions is the same across categories of group.	Independent-Samples Mann-Whitney U Test	.290[1]	Retain the null hypothesis.
2	The distribution of Change in non-inflamed lesions is the same across categories of group.	Independent-Samples Mann-Whitney U Test	.193[1]	Retain the null hypothesis.
3	The distribution of Change in total lesions is the same across categories of group.	Independent-Samples Mann-Whitney U Test	.193[1]	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

[1]Exact significance is displayed for this test.

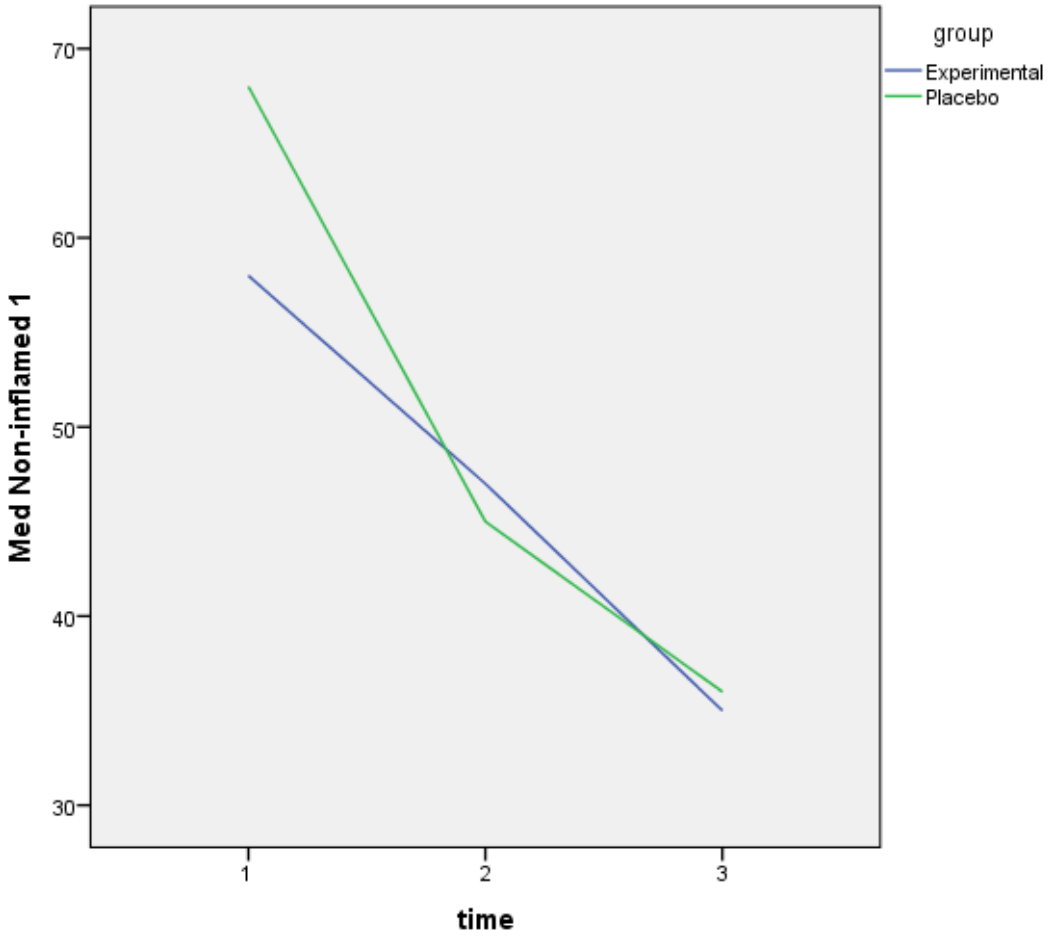

Figure 8: Equivalence of the rate of change in the median number of non-inflamed lesions in the experimental (complex) and control (placebo) groups over time.

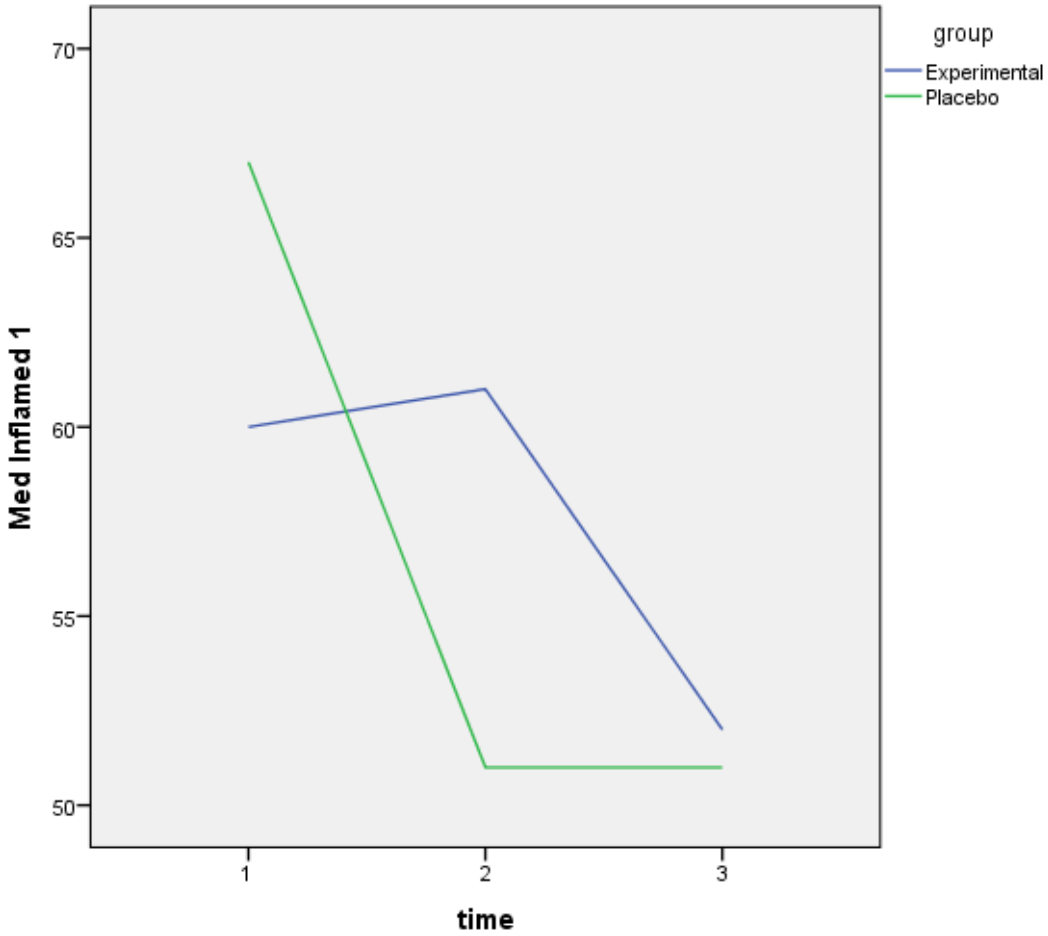

Figure 9: Equivalence of the rate of change in the median number of inflamed lesions in the experimental (complex) and control (placebo) groups over time.

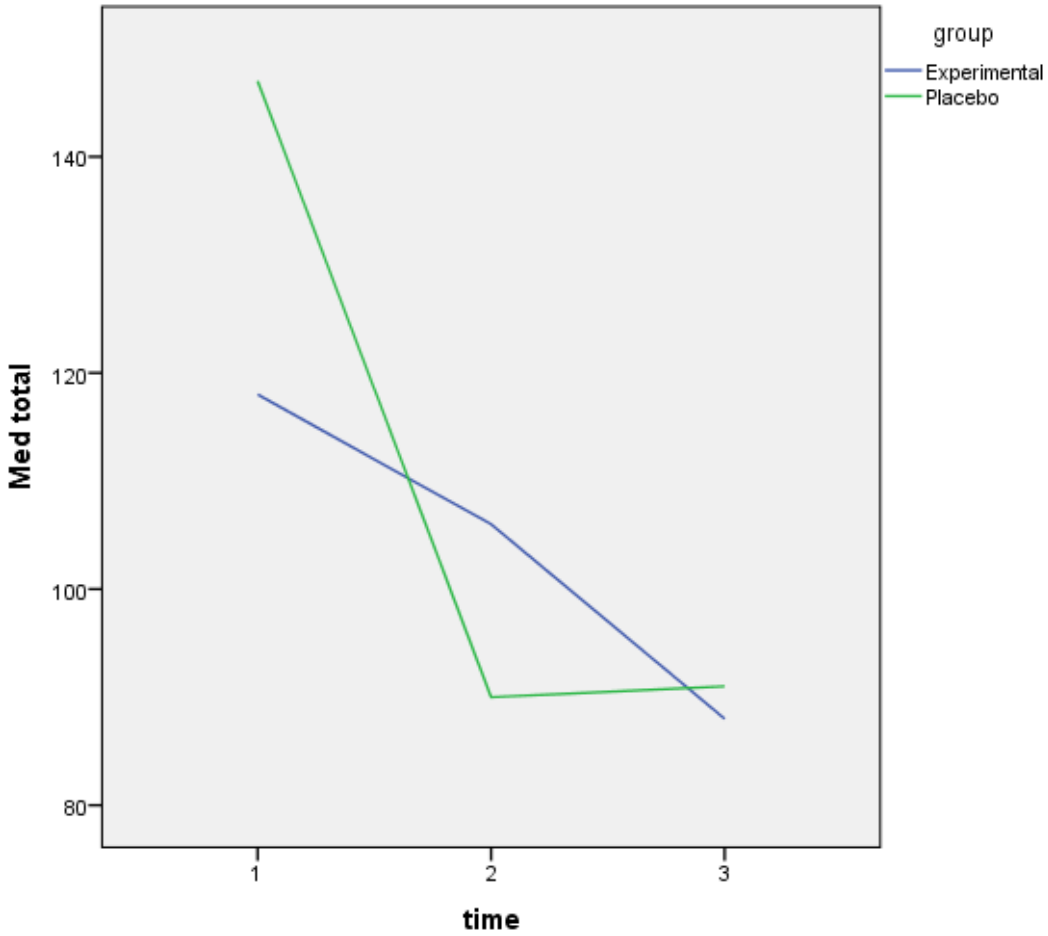

Figure 10: Equivalence of the rate of change in the median total number of acne lesions in the experimental (complex) and control (placebo) groups over time.

4.5 SUMMARY AND CONCLUSION

4.5.1 Non-inflamed lesions

There was no evidence of an effect of the homoeopathic complex compared to the placebo in males, and in females the placebo was borderline non-significantly more effective than the intervention. Therefore the null hypothesis is retained for males and females.

4.5.2 Inflamed lesions

There was no evidence of an effect of the homoeopathic complex compared to the placebo in males or females. Therefore the null hypothesis is retained for males and females

4.5.3 Total acne lesions

There was no evidence of an effect of the homoeopathic complex compared to the placebo in males, and in females the placebo was more effective than the homoeopathic complex. Therefore, the null hypothesis is retained for males and females

There is evidence that in females the placebo is more effective than the homoeopathic acne complex (intervention) in terms of total acne lesions ($p = 0.034$). On the whole, this study has shown no evidence for a beneficial effect of the homoeopathic acne complex. Therefore, the null hypothesis is retained. The findings of this study indicate that the homoeopathic complex is not effective in the treatment of acne vulgaris.

CHAPTER 5
DISCUSSION

The aim of this study was to determine the efficacy of a homoeopathic complex (*Kalium bromatum* 9CH, *Natrum muriaticum* 9CH, *Selenium* 9CH, *Sulphur* 9CH and *Thuja occidentalis* 9CH), compared to placebo, in the treatment of acne vulgaris. The Leeds counting technique (Burke and Cunliffe, 1984:87-92) was used to assess the response to treatment of facial acne vulgaris, by measuring the rate of change in the number of non-inflamed, inflamed and total number of acne lesions. A total of 37 participants between the ages of 18 and 31 were recruited from the Greater Durban area and randomly assigned to either an experimental (homoeopathic complex) or control (placebo) group, according to gender stratification. Three participants dropped out from this study, 2 males and 1 female, so the final sample number was 34. After unblinding, in the final sample, the experimental group consisted of 7 males and 10 females, while the control group consisted of 9 males and 8 females, due to dropouts. These numbers still reflected the overall gender stratification of the sample.

The majority of acne lesions recorded during the course of this clinical trial were blackheads, whiteheads, papules and pustules. The minority of lesions were nodules, cysts and deep pustules.

5.1 DISCUSSION OF STATISTICAL ANALYSIS AND RESULTS INVOLVING GENDER CLASSIFICATION

5.1.1 Non-inflamed lesions

There was no evidence of an effect of the homoeopathic complex compared to placebo in males. Both groups showed a similar median reduction in the number of non-inflamed lesions. Therefore, it was concluded that there was no significant difference between the experimental (complex) and control (placebo) groups in terms of the change in non-inflamed lesions ($p = 1.000$). However, in females, there was a marginally non-significant difference between the experimental

(complex) and control (placebo) group in terms of the change in the number of non-inflamed lesions (p = 0.055). The placebo group experienced a higher mean reduction than the complex group, meaning that the placebo was borderline non-significantly more effective than the complex.

5.1.2 Inflamed lesions

In males, although the control (placebo) group showed a slightly higher median reduction than the experimental (complex) group, there was no significant difference between the complex and placebo groups in terms of the change in the number of inflamed lesions (p = 0.606). In females, the placebo group also showed a slightly higher median reduction in the number of inflamed lesions than the complex group. However, there was no significant difference between the complex and placebo groups in terms of the change in the number of inflamed lesions in females (p = 0.146). Therefore, there was no effect of the homoeopathic complex compared to the placebo in males or females.

5.1.3 Total acne lesions

There was no significant difference in the reduction in the total number of acne lesions between the experimental (complex) and control (placebo groups) in males (p = 1.000). The complex group showed a slightly higher reduction on average than the placebo group, but it was concluded that there was no evidence of the effect of the homoeopathic complex compared to placebo in males. The significant observation to note was that in females, the reduction in the total number of acne lesions was greater in the control (placebo) group than the experimental (complex) group (p = 0.034), indicating that the placebo was significantly more effective than the homoeopathic complex in females in terms of a significant reduction in the total number of acne lesions, which can be demonstrated by an average reduction of 39.5 lesions in the experimental group and a reduction by 72 lesions in the placebo group, in females.

5.2 DISCUSSION OF STATISTICAL ANALYSIS AND RESULTS WITHOUT GENDER CLASSIFICATION

The study concluded that there was no significant difference in the number of non-inflamed, number of inflamed and total number of acne lesions between the experimental (complex) and control (placebo) groups. Both groups showed a similar reduction when compared to each other, with respect to the variables of interest (i.e. the number of non-inflamed, number of inflamed and total number of acne lesions). The p values for comparison between groups, without gender classification, were as follows: non-inflamed lesions ($p = 0.193$), inflamed lesions ($p = 0.290$) and total number of acne lesions ($p = 0.193$). As a result, the null hypothesis was retained. The study concluded that the homoeopathic acne complex is not effective in the treatment of acne vulgaris. This conclusion supports the findings by Smolle (2003:96) that only a few controlled trials have been conducted in homoeopathy, most of which have negative results. Smolle's conclusion is that at the present stage of knowledge there is no sound evidence for homoeopathy in the treatment of skin diseases which would justify its wide application.

5.3 DISCUSSION OF THE PLACEBO EFFECT

It is interesting to note that in most cases the placebo group showed a slightly higher decrease in the number of acne lesions than the complex group, although only in females was this decrease statistically significant. However, it is a well known fact that a placebo is pharmacologically inactive. According to Chauhan and Gupta (2007:53), a placebo is a pharmacologically inert substance, having no physiological action. How then could this placebo substance have caused a significant improvement in the total number of acne lesions in females when compared to females of the experimental (complex) group, and how could the experimental (complex) and control (placebo) groups show a similar reduction in the number of acne lesions when compared to each other? This can be attributed to the placebo effect. As pointed out by Castro (2007), trials with placebo groups may produce indirect benefits, e.g. participants in the placebo control group frequently benefit from the attention they receive from investigators of the study

and staff. They also benefit from the ancillary treatments and the diagnostics which they receive as part of the trial.

According to Chauhan and Gupta (2007:53), a placebo will produce a positive effect on certain people who have certain medical problems (medical problems with a mind body link, e.g. depression, pain, asthma, and Parkinson's disease), in certain settings some of the time. Chauhan and Gupta (2007:53) also state that in a clinical trial, a positive placebo reaction will occur if a patient believes that the medicine (placebo) will assist him or her, and if the system of the patient has the capacity to get well. In this case, resolution of the symptom will occur.

A study was conducted to determine whether placebo responses could be explained by characteristics of the patient, the practitioner, or their interpersonal interaction, i.e. patient and practitioner influences on the placebo effect in the treatment of irritable bowel syndrome. The intervention was placebo acupuncture. Patients (289 in number) were randomized for 3 weeks to a waitlist group (symptoms were monitored but no treatment was administered), limited group (placebo acupuncture delivered by a neutral practitioner twice a week for a total of 6 sessions) and augmented group (placebo acupuncture delivered by a warm, empathic practitioner twice a week for a total of 6 sessions). It was concluded that the placebo response was influenced by gender (female) and personality (patient extraversion, agreeableness and openness to experience) of the patient. However, this occurred in the augmented group only, suggesting that, to the degree that the placebo effect is evoked by the patient-practitioner relationship, the patient personality characteristics will be associated with the placebo response. However, if there is minimal patient-practitioner interaction and if the placebo effect is evoked mainly through the placebo device or placebo medication, the patient personality characteristics will be less important in predicting the placebo response (Kelley, Lembo, Ablon, Villanueva, Conboy, Levy, Marci, Kerr, Kirsch, Jacobson, Riess and Kaptchuk, 2009).

In this clinical trial, it was possible that participants in the placebo group experienced the placebo effect. However, there could have been other factors that influenced the results of this study, which will be discussed in this chapter.

5.4 FACTORS THAT COULD HAVE POSSIBLY AFFECTED THE OUTCOME OF THE STUDY

The placebo effect as a possible factor that could have affected the outcome of this study, was discussed earlier. It is important to note that the researcher did not advise participants to change their lifestyle during the course of the clinical trial. Therefore, negative lifestyle factors in place at the start of the study and continued during the course of the study, e.g. diet, environment exposure (which includes types of weather the participant was exposed to) and stress could have also affected the outcome. According to a study by Ghodsi, Orawa and Zouboulis (2009:2136), recognised risk factors for moderate to severe acne were increasing pubertal age, seborrhoea, premenstrual phase, mental stress, and sweet and oily food. Some of the possible factors will now be discussed.

5.4.1 Stress

Chiu, Chon and Kimball (2003:897) state that changes in acne severity correlate largely with increasing stress while Pawin et al. (2007:313) state that acne has a huge impact on the well-being and quality of life of acne sufferers.

Since many of the research participants in this clinical trial were students, stress could have been a factor because many of the participants would have had tests and exams during the course of their treatment periods. These increased levels of stress could have exacerbated the acne condition preventing a significant improvement in the acne lesions of participants in the experimental group. It is important to note that some participants did actually report that examination stress had caused an increase in their acne cutaneous eruptions according to their subjective assessment.

5.4.2 Compliance with treatment

Although all participants were adequately reminded at every consultation to take their medication daily on time, and participants were also asked to bring their tablet containers to the follow-up consultations to determine compliancy of treatment, the researcher could not enforce the adherence to treatment or the efficiency with which participants were compliant with treatment or not. Participants could have forgotten to take the tablets on certain days, forgotten to take the tablets on time or taken their tablets close to meals despite the instructions on their “How to take homoeopathic medication” handout (Appendix I1). All these issues of non-compliance could have significantly affected the outcome of the study. Levatin (2009:143) states that acne is a long-standing and chronic condition and therefore difficult to treat homoeopathically as resolution will take time and requires follow-up consultations. She goes on to say that the problem occurs mainly in adolescents who may not be compliant with homoeopathic treatment. Morrison (1998:471) states that the homoeopathic treatment is commonly complicated by the fact that the main sufferers of acne are those people who are least able to tolerate the condition and its homoeopathic treatment, mainly teenagers. Although the majority of the participants in this study were not teenagers, the fact is that non-compliance can affect the outcome of treatment (Nguyen and Su, 2011:125).

5.4.3 Counting of lesions

Counting was performed by the researcher and verification of counting was performed by one of two qualified and registered homoeopaths. Although this was the case, one cannot rule out the possibility of an error in the counting of lesions. Burke and Cunliffe (1984:87) state that lesion counting is not easy and therefore perfection takes time.

5.4.4 Diet

According to Gibbon (2005:191), diet has only a minor role in the aetiology of acne. However, many acne participants believed that exacerbation of their acne

condition was caused by certain aspects of their diet. These included food such as nuts, chocolate, fatty food, fried food, eggs, cakes, biscuits, spices, coffee and tea (El-Akawi et al., 2006b:840).

Many of the acne participants in this clinical trial confirmed to the researcher that their diet consisted of chocolate, cakes, fatty food, coffee and tea. Some also reported to the researcher that they felt their diet could have worsened their acne condition. It is therefore concluded that the diet of these participants may have exacerbated their acne and as a result prevented improvement of acne and affected the outcome of this study.

5.4.5 Weather

In a study conducted by El-Akawi et al. (2006b:840, 842), acne patients of both sexes believed that hot weather from exposure to sunlight and summer heat aggravated their acne condition while many acne patients believed that sweating excessively also aggravated their acne. Two-thirds of acne patients mentioned that their acne improved during winter.

In this clinical trial, many participants mentioned to the researcher that sunlight had a direct effect on their acne by causing sweating, which increased the number of acne lesions on their faces. The participants also claimed that the sweating made them feel uncomfortable. There were a few participants who mentioned that cold weather caused cracking and drying of their skin, worsening the acne while others mentioned they preferred cold weather to hot weather. It is therefore evident that hot or cold weather exposure could have possibly affected the outcome of this study.

5.4.6 Premenstrual factors

In a study conducted by El-Akawi (2006b:840, 844), a large number of female acne patients believed that premenstrual factors had aggravated their condition while only a few noticed no effect of menstruation on their acne.

In this clinical trial, many female participants claimed that there was a flare-up of their acne before and during menstruation. Therefore, premenstrual factors could have possibly affected the outcome of this study in females.

5.5 RELATIONSHIP TO OTHER ACNE STUDIES

The previous acne studies at Technikon Natal/Durban University of Technology that used the Leeds counting technique were clinical trials conducted by McDavid (1994), Lee (1997), Van Niekerk (1999), Govender (2003) and Nijland (2005). The results of this study was that there was no significant difference in the number of non-inflamed ($p = 0.193$), number of inflamed ($p = 0.290$) and total number of acne lesions ($p = 0.193$) between the experimental (complex) and control (placebo) group (both groups showed a similar reduction) and were therefore similar to results of studies conducted by of Lee (1997) and Nijland (2005).

Lee (1997) determined the role of a homoeopathic complex (*Silicea* 30CH, *Selenium* 9CH, *Hepar sulphuris* 30CH, *Kalium bromatum* 9CH, *Arctium lappa* 3CH, *Pulsatilla* 30CH) compared to placebo, in the treatment of acne vulgaris. There was no significant difference within and between groups over the 5 consultations, indicating that the homoeopathic complex was not effective in treating acne. The results were similar to this study as there was no significant difference in the number of acne lesions between groups and it was concluded that the homoeopathic complex in this study was not effective in the treatment of acne vulgaris. However in this study, there was a significant reduction in the number of lesions within each group.

Nijland (2005) investigated the use of *Kalium bromatum* 30CH in the treatment of acne vulgaris and, as there was no significant difference between the experimental and placebo groups, he concluded that *Kalium bromatum* 30CH was not effective in the treatment of acne vulgaris, in terms of clinical manifestations. This study also concluded that the homoeopathic complex was not effective in the treatment of acne vulgaris.

However, a study conducted by Bekker (2004), which investigated the effect of Testis Compositum® (a preparation that contains 16 homoeopathic remedies, 5 suis organ preparations, *Acidum ascorbicum* D6 and *Cortisonum aceticum* D13) concluded that Testis Compositum® had a significant effect in improving acne vulgaris. This was the only homoeopathic complex study to show a significant result with respect to the improvement of acne vulgaris. This finding was contrary to the findings of this clinical trial which reveal that the homeopathic complex did not significantly improve the acne lesions when compared to the placebo group. Both groups in this study showed a similar reduction.

It is interesting to note that some studies have produced positive results. The homoeopathic simillimum study conducted by McDavid (1994) produced statistically significant results, in terms of acne improvement. He concluded that there was a statistically significant improvement in the clinical manifestations of acne in the simillimum group ($p = 0.006$). Van Niekerk (1999) also concluded from the results of her study that miasmatic treatment was as effective as simillimum treatment as there was no statistically significant difference in the reduction of lesions between the simillimum and miasmatic groups (both groups showed a similar reduction). Govender (2003) discovered that a herbal complex worked as well as the simillimum as both these groups showed a similar reduction in acne lesions.

The results of these studies showed that wherever the simillimum was given as treatment there was a reduction or improvement in acne lesions. The study conducted by McDavid (1994) produced a result opposite to the results of this study. Whereas the study conducted by McDavid (1994) showed that the homoeopathic simillimum was effective in the treatment of acne, this study showed that the homoeopathic complex was not effective in the treatment of acne vulgaris. However, one of the drawbacks of the studies conducted by Van Niekerk (1999) and Govender (2003) was that there was no placebo group, so one cannot assess whether the improvements were due to the treatment effect or placebo effect.

A study was conducted at an outpatient clinic at Associação Paulista de Homeopatia (APH), São Paulo, Brazil, to assess the effectiveness of individualised homoeopathic treatment in a public outpatient clinic, for dermatological complaints such as atopic dermatitis, psoriasis, chronic urticarial, acne, etc. The study concluded that individualized homoeopathic treatment was effective in 59% of patients. There was a significant improvement or resolution of the dermatological complaints and also improvement of the psychological and general state, without an emergence of other pathological features, i.e. no evidence of suppression (Waisse-Priven et al., 2009:149, 152). The results of this study, which indicated that individualised homoeopathic treatment (mental, general and local signs and symptoms) or the simillimum produced effective or significant results, was contrary to the outcome of this homoeopathic acne complex study which stated that the homoeopathic complex (prescribed only on the basis of physical pathology) was not effective in the treatment of acne vulgaris.

5.6 SIGNIFICANCE OF THE FINDINGS OF THE STUDY

Comparison of this study with other previous acne studies indicates that the homoeopathic simillimum, in the majority of clinical trials, produced a significant improvement of acne lesions, as compared to studies that utilised a single remedy or a homoeopathic complex prescribed to participants on the basis of physical pathology, which showed that such treatments are not effective in the treatment of acne vulgaris.

The homoeopathic complex used in this clinical trial consisted of remedies prescribed to the participants on the basis of the physical signs and symptoms of acne vulgaris. The complex prescribed to the participants did not consider mental or emotional symptoms of the participant. Morrison (1998:405) states that the characteristics of skin eruptions may provide a clue to the proper constitutional treatment, but are among the least reliable symptoms on which to prescribe.

One of the strong points of homoeopathy is the treatment of chronic disease (with deep constitutional treatment). By treating the disease at a deeper level, the sick person's system can be assisted to remove the disease or minimise it. As a result, there will be no further acute attacks or lesser attacks which are far milder (Bloch and Lewis, 2003:34).

Homoeopathy has a holistic approach. Each individual will characteristically and individually experience or display his or her illness. Therefore, a specific medicine with a similar pattern will be required to treat that specific person who has a specific suffering. When the underlying weakness of the constitution is treated it can assist to build up the wellbeing, strength and illness resistance of the individual (Bloch and Lewis, 2003:25, 27).

Therefore, from the above discussion, it is concluded that the simillimum or constitutional treatment (which takes into account the mental, emotional, general and physical symptoms) of homoeopathy is a much better option than the prescription of a homoeopathic complex prescribed to patients on the basis of physical signs and symptoms only.

CHAPTER 6
CONCLUSION AND RECOMMENDATIONS

This study aimed to determine the efficacy of a homoeopathic complex (*Kalium bromatum* 9CH, *Natrum muriaticum* 9CH, *Selenium* 9CH, *Sulphur* 9CH and *Thuja occidentalis* 9CH) in the treatment of acne vulgaris. It was found that the homoeopathic complex was not effective in the treatment of acne vulgaris. There was no significant difference in the total number of acne lesions between the experimental and control group ($p = 0.193$). The results of this study was similar to acne studies conducted by Lee (1997), who found that there was no significant improvement between groups after treatment with a homoeopathic complex, and Nijland (2005), who concluded that *Kalium bromatum* 30CH, prescribed according to physical symptoms, was not effective in the treatment of acne vulgaris (all p values were greater than 0.05). However the results of this study was different from a study conducted by McDavid (1994), who found that the homoeopathic simillimum significantly improved the clinical manifestations of acne vulgaris ($p = 0.006$), while Van Niekerk (1999) found that miasmatic treatment was as effective as simillimum treatment, and Govender (2003) concluded that the herbal complex worked as well as the simillimum. Therefore, homoeopathic simillimum treatment appears to be a better option compared to homoeopathic treatment based only on physical signs and symptoms, e.g. homoeopathic complexes.

6.1 RECOMMENDATIONS

- More simillimum studies should be conducted in the future, but compared to a placebo, like the study conducted by McDavid (1994). This would determine if the results are actually due to the simillimum or the placebo effect. More effective simillimum studies could provide a verified homoeopathic therapeutic option for acne patients and reduce the cost burden of acne vulgaris due to the inexpensive nature of homoeopathic medication.

- This study should be repeated with a well-being perception questionnaire to also measure the patients' subjective responses to treatment.
- This study should be repeated with the same homoeopathic complex but the complex should be compared to a homoeopathic simillimum and placebo, in the same study. The placebo will serve as a control to determine if results are due to the complex or simillimum or due to the placebo effect. This study should employ a large sample size.
- Future homoeopathic clinical trials on acne should use a large sample size. This is because a larger sample size would mean that more of the population with acne can participate in the study and results can be based on a broader patient number, producing results with a better evaluation of the therapeutic action of homoeopathic medication on acne vulgaris.
- Future homoeopathic clinical trials should consider increased frequency of dose administration e.g. asking participants to take the homoeopathic medicines twice or thrice daily, and also be of a longer duration, e.g. between 8 to 12 weeks treatment period for each participant, providing sufficient stimulus, and giving sufficient time, to produce a positive therapeutic effect.
- With respect to treatment compliance, participants in future acne studies should be reminded to take their medications daily. This can be achieved by the researcher calling them daily by means of a telephone or cellular phone, or by sending them reminders by cellular telephone messaging. This may ensure effective treatment compliance and therefore better results. Knutsen-Larson et al. (2012:103) recommend the use of cellular phone and internet technology to promote treatment regimen adherence through the use of patient reminders.

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APPENDICES

APPENDIX A

Do you suffer from

ACNE?

If you suffer from acne vulgaris and are between the ages of 13 and 35 you will receive treatment at no cost should you qualify for the study

Research is currently being done at the Durban University of Technology Homoeopathic Day Clinic. If you would like to participate in the study or would like to know more……

Contact: Sameer Ally on *[deleted]*

APPENDIX B1

INFORMATION LETTER

TITLE OF RESEARCH PROJECT: The efficacy of a homoeopathic complex (*Kalium bromatum* 9CH, *Natrum muriaticum* 9CH, *Selenium* 9CH, *Sulphur* 9CH and *Thuja occidentalis* 9CH) in the treatment of acne vulgaris.

NAME OF SUPERVISOR: Dr Richard Steele (BA HDE) (M. Tech. Hom.)

NAME OF RESEARCH STUDENT: Sameer Ally

Dear Participant

I hope that you are well. Thank you for taking time to read this information letter. You are kindly invited to take part in a clinical trial.

I am a Master's Degree in Technology (M. Tech.) student in Homoeopathy and in order to qualify I am required to complete a research project and dissertation. With your assistance and co-operation I will be able to perform a research project on the treatment of acne vulgaris with a homoeopathic complex, which could be helpful to many others besides yourself.

This clinical trial will take place at the Durban University of Technology Homoeopathic Day Clinic on weekday afternoons. Treatment will be supervised by a qualified and registered homoeopath.

In order to be included in this clinical trial, you will need to fulfil the following criteria:

- Be male or female.
- Be of any race.
- Be between the ages of 13 and 35.
- You must have ACNE VULGARIS. This will be diagnosed by the researcher according to the diagnostic criteria of the BMJ Evidence Centre. A minimum of 8 or more non-inflamed and/or inflamed lesions are required.
- You must be off any form of acne treatment (allopathic, homoeopathic or herbal) for at least 4 weeks before entrance to the study.
- You must be able to converse in English as all consultations will be conducted in English.

- You must be a resident in the Greater Durban area for easy access to the Durban University of Technology Homoeopathic Day Clinic.

The following criteria will exclude you from participation in this clinical trial:

- If you have acne fulminans, conglobate acne or acne rosacea (as diagnosed by the researcher with the help of the designated clinician).
- If you have sandpaper acne, where hundred or more lesions occur on the forehead and are almost impossible to classify correctly.
- If you are pregnant or breast feeding.
- If you are on antibiotic treatment for any reason.
- If you are on dermatological therapy (medicinal or surgical), e.g. treatment for eczema, boils, etc.
- If you are on any hormonal therapy, e.g. cortisone therapy, anti-androgens and oral contraceptives.
- If you are on vitamin and mineral therapy, or Schussler tissue salts.

More information about this clinical trial:

- The duration of the study will be 6 weeks, which will contain 3 consultations.
- You will be accepted into this study once you have read this information letter, fulfilled the above inclusion and exclusion criteria and signed a consent form.
- You will also be required to fill in a form that contains all your personal details (telephone number, address, etc.) before the first consultation. This will be kept private.
- During the first consultation, the researcher will take a full case history, perform a full physical examination, and count and record the number of pimples on your face on a separate sheet with a number, not your name. The first consultation will be 90 minutes.
- If you are wearing make-up, you will be asked to clean this off before the pimples are counted.
- At the end of the first consultation, you will be given the treatment medication (homoeopathic complex or placebo – you will not know which it is because they will look and taste the same), and instructions on how to take one tablet a day. All medication will be in the form of tablets.

- During the second (3 weeks after the first consultation) and third (3 weeks after the second) consultations, your acne will be reviewed and the number of acne pimples on your face will again be counted and recorded.
- The second and third consultations will be an hour each. You will be required to bring your tablet container to the second and third consultations.
- All your information from each consultation will be kept strictly confidential. Consultation notes will not have your name on.

This is a double-blind placebo controlled clinical trial. What does this mean?

- A placebo is a substance that looks and tastes the same as the acne complex medication, but contains no medicine. If you still do not know what a placebo is, the researcher will explain it to you. The reason for using a placebo is to find out if the positive results are because of taking the homoeopathic complex or the effect of taking a tablet daily.
- Double-blind means that neither the researcher nor the participant knows whether the acne complex or placebo is dispensed at the end of the first consultation.

There is a 50% chance that you will receive a complex or 50% chance you will receive a placebo.

A total of 34 participants will take part in this study of which 17 participants will receive the complex and 17 the placebo. Participants will be randomly assigned to a complex group (17 participants) and placebo group (17 participants).

Homoeopathic medicines are regarded as very safe because of the high dilutions used. However, sometimes, it is possible that at first your acne pimples will get worse for a brief period of time after taking the medicine and then either return to their previous state or improve. This means that you are sensitive to the medicine and is not considered a side effect. Please phone the researcher if you are concerned about any symptoms you may be experiencing that are worrying you, and he will contact the supervisor who will arrange the appropriate assessment and assistance.

At the end of the clinical trial, participants who received the placebo will receive the homoeopathic acne complex that the other group received during the study, that is, one free treatment.

This study will not cost you anything and participation in this study is completely voluntary. You can withdraw from this study at any time.

If you have any queries or concerns regarding this clinical trial, please contact me or my research supervisor at any time.

Sameer Ally *[phone number deleted]*

Dr Richard Steele *[phone number deleted]*

Thank you for your assistance.

Department of Homoeopathy

Durban University of Technology

APPENDIX B2

INCWADI YOKUZINIKELA KWESIGULI

INQIKITHI YOCWANINGO: Amandla lwengxibemithi ye-homeopathy (*Kalium bromatum* 9CH, *Natrum muriaticum* 9CH, *Selenium* 9CH, *Sulphur* 9CH ne *Thuja ocidentalis*) ekwelapheni izinduna kwisikhumba.

IGAMA LOMHLOLI: UDokotela Richard Steele (BA HDE) (M. Tech. Hom.)

IGAMA LOMFUNDI OWENZA UCWANINGO: Sameer Ally

Lunga elithandekayo

Ngiyathemba uyaphila. Siyabonga ngokuthatha isikhathi sakho ufunda lencwadi. Sicela ukukumema ekubeni yinxenya yalolucwaningo esilwenzayo kwezempilo.

Mina ngineziqu zemfundo ephakeme enfundweni yobucwepheshe, ngifundela ubudokotela (ihomoeopathy) (Master's Degree in Technology: Homoeopathy) kwezokolapha ngokwemvelo. Ukuze ngigogode kahle kudingeka ngenze umsebenzi omkhulu wocwaningo ngokuphelele kulo mkhakha. Lomsebenzi uzokwenzeka ngempumelelo ngosizo lwakho nangokubambisana osekungasiza nabanya abaningi abaningi abanezinkinga yezinduna ebusweni.

Lokhu kuhlola kuzokwenzeka esikhungweni semfundo eThekwini Durban University of Technology Homoeopathic Day Clinic (umtholampilo), njalo phakathi nezinsuku sesonto ntambama. Lokukuhlola kuzokwenzeka ngaphansi komphathi wocwaningo nomfundi.

Ukuze ulungele ukuba kulokhu kuhlola, kumele ube naloku okulandelayo:

- Owesilisa noma owesifazane
- Owanoma uluphi uhlanga
- Yiba neminyaka enguwu 13 kuya ku 35
- Kufanele ube nonenkingha yezinduna esikhumbeni sakho, okunenani sikuphathe izinyanga eziyisishagalolunye. Udokotela wocwaningo uzozihlola izinduna zakho.
- Kufalele ungabibikho ohlelweni lowelashwa izinduna ezisebuseni okungenani amasonto amane.
- Yiba okwaziyo ukukhuluma isilunga ngoba ulimi olusetshenziswayo isingisi.
- Kufanele ube aqhamuka eThekwini namaphethelo ukuze ukwazi ukufinyelela kalula esikhungweni socwaningo esiseThekwini – Durban University of Technology Homoeopathic Day Clinic (umtholampilo).

Lokhu okulandelayo kuyizizathu zokuba ungangeni kulokhu kuhlolwa kwezempilo:

- Uma unezinduna esiphongweni ezimahadla eziyikhuli noma ngaphezulu futhi ezingaqondakali ezizotholwa udokotela wocwaningo.
- Uma ukhulelwe noma uncelisa.
- Uma ungaphansi kohlelo lokwelashwa noma ngaba yisiphi isizathu.
- Uma ungolashwelwa isikhumba ngenxa yokusha noma unekinga zesikhumba.
- Uma usebenzisa imithi ethiba ukukhulelwa noma o-cortisone.
- Uma kukhona amakhambi owasebenzisayo ukuvuselela imizimba (amavitamin) ukuze ubukeke kangcono.

Olunye ulwazi mayelana nalokhu kuhlolwa kwezempilo:

- Loluhlelo locwaningo luzothatha amasonto ayisithupha, okuyoba namahlandla amathathu okubonana nodokotela.
- Kulolucwaningo uyomukeleka kuphela uma usufunde lencwadi yolwazi ngokwanele waneliseka ngezinto ezikufakayo nezikukhiphayo kuloluhlelo locwaningo kwezempilo, bese ugcwalisa lefomu lokwaneliseka.
- Kuyodingeka futhi ukuba ugcwalise ifomu elinayo yonke lemininingwane yakho, ngaphansi kokubonana nodokotela lokho kuyocinwa kuyimfihlo.
- Esigabeni sokuqala udokotela ocwaningo uzokwenza umsebenzi wokuhlola okunzulu abale nezinduna ezisebusweni ebala konke ephepheni eliseceleni, nakho konke okunye lokho kuyothatha imizuzu engamashumi ayisithupha shagalolunye.
- Uma kukhona okugcoba ebusweni okokuphaphatha isikhumba uyocelwa ukuba ugeze ngaphambi kokubalwa kwezinduna ezisebusweni.
- Ekupheleni kwesigaba sokuqala ubonene nodokotela uyonikezwa umshanguzo wokwelapha isikhumba ngokwemvelo noma amaphilisi angena mithi (ngeke wakwazi ukuhlukanisa ngoba ubukeka futhi unambitheka ngendlela efanayo), kanye nomyalelo wokuba ugwinye iphilisi elilodwa ngosuku.
- Esigabeni sesibili nesithathu (okuyolilukaniswa ngamasonto amathathu) ubonana nodokotela ongowocwaningo uyobe esikubekisisa ezibala izinduna.
- Isigaba sesibili nesithathu ubonana nodokotela siyothatha ihora (imizuzu engamashumi ayisithuphi) kuyodingeka ubuye uphethe isitsha obubufake kuso amaphilisi.
- Lonke ulwazi olutholakala ngenkathi unodokotela iyocinwa iyimfihlo.

Kuyoba khona idouble blind placebo kulolucwaningo, kuchaze ukuthini lokhu?

- I-placebo yinto ebukeka futhi enambitheka njengomuthi kodwa akusiyo umuthi wangempela. (Uma ungaqondi ukuthi i-placebo yini uyophinda ucele ukuchazelwa).

- I-doubleblind ukungaboni okubili kusho ukuthi isiguli nodokotela wocwaningo bobabili abazi ukuthi wena unikwe muthi nqo noma i-placebo.

Lapho ubonana nodokotela okokuqala unethuba elingu 50% lokuthola umuthi ngqo nethuba elingu 50% lokuthola i-placebo.Uyonikwa umuthi noma i-placebo ngokungenhloso.

Kubantu abangamashumi amathathu nane abazoba yingxenye yalolucwaningo, abayishumi nesikhombisa bazothola imvubela yemithi abanye abayishuminane bathole i-placebo.

Ukwelashwa ngemithi enengxube yemvelo kuphephile ngenxa yokuphuphutwa kaningi. Nokuba kwesinye isikhathi kungenzeka uma usebenzisa okokuqala izinduna zivumbuke kakhulu okwesikhashana emuva kwalokho isimo sibuyele kokujwayelekile noma zishe ebusweni

kubengcono. Lokhu kusho ukuthi lamakhambi asebenza ngamandla esikhumbeni sakho. Uyacelwa ukuba ufonele umcwaningi noma udokotela ngokushesha uma kunezinto ozisolayo nezingakuphathi kahle, yena uyobe esexhumana nophethe ucwaningo ukuze uzothola ukusizakala ngokushesha.

Ngasekugcineni kokuhlolwa kwalolucwaningo ohlolwayo uyobe esethola i-placebo esizayo ekwelapheni inkinga yezinduna esikhumbeni ebikade itholwa abakwelinye iqembu.

Lokhu kuhlola ngeke ukukhokhele imali. Kanti uyazi khethela ena ukuba yingxenye yalolucwaningo. Ungahoxa noma inini uma uzwa ungasakhululekile ngakho.

Uma unemibuzo noma unganelisekile udinga ulazi ngithinte ngocingo noma uthinte umphathi wocwaningo lulenombolo.

Sameer Ally *[phone number deleted]*

UDokotela Richard Steele *[phone number deleted]*

Siyabonga ngosizo lwakho.

Umnyango weHomoeopathy

Iyunivesi yaseThekwini yobuchwepheshe (Durban University of Technology)

APPENDIX C1

INFORMED CONSENT FORM

TITLE OF RESEARCH PROJECT: The efficacy of a homoeopathic complex (*Kalium bromatum* 9CH, *Natrum muriaticum* 9CH, *Selenium* 9CH, *Sulphur* 9CH and *Thuja occidentalis* 9CH) in the treatment of acne vulgaris.

NAME OF SUPERVISOR: Dr Richard Steele (B.A. H.D.E.) (M. Tech. Hom.)

NAME OF RESEARCH STUDENT: Sameer Ally

Date: _____

PLEASE CIRCLE THE APPROPRIATE ANSWER

1. Have you read the information sheet? YES/NO
2. Have you had the opportunity to ask questions regarding the study? YES/NO
3. Have you received satisfactory answers to your questions? YES/NO
4. Have you had the opportunity to discuss this study?Y YES/NO
5. Have you received enough information about this study? YES/NO
6. Who have you spoken to? _____

   Do you understand the implications of your involvement in the study? YES/NO
7. Do you understand that you are free to withdraw from this study? YES/NO
   a) at any time, and
   b) without having to give reasons for withdrawing
9. Do you agree to voluntarily participate in this study? YES/NO
10. Do you understand that you may receive a placebo during this study? YES/NO
11. Do you understand the difference between a placebo and a homoeopathic treatment? YES/NO
12. **If you answered "NO" to any of the above questions please obtain the information before signing.**

PATIENT NAME: _____

SIGNATURE: _____

WITNESS NAME: _____

SIGNATURE: _____

RESEARCH STUDENT: _____

SIGNATURE: _____

APPENDIX C2

INCWADI EVUNYE NGOKUBONISANA

INQIKITHI YOCWANINGO: Amandla lwengxibemithi ye-homoeopathy (*Kalium bromatum* 9CH, *Natrum uriaticum* 9CH, *Selenium* 9CH, *Sulphur* 9CH ne *Thuja occidentalis*) ekwelapheni izinduna kwisikhumba

IGAMA LOMHLOLI: UDokotela Richard Steele (B.A.H.D.E.) (M. Tech. Hom.)

IGAMA LOMFUNDI OWENZA UCWANINGO: Sameer Ally

Usuku: _____

FAKA ISIKOKELA EMPENDULWENI EFANELE

1. Ngabe uyifundile imininingwane ephepheni locwaningo? YEBO/CHA
2. Ngabe usitholile isikhathi sokubuza imibuzo emayelana nalesisifundo? YEBO/CHA
3. Ngabe uzitholile izimpendulo ezikwenelisayo zemibuzo yakho? YEBO/CHA
4. Ngabe ulithlile ithuba lokuxoxisa mayelana nalesisifundo? YEBO/CHA
5. Ngabe uthole incazelo eyanele mayelana nalesisifundo? YEBO/CHA
6. Ngabe ukhulume nobani?
   _____
7. Ngabe uyaqonda imiphumela yokuzimbadakanya kwakho kulesisifundo? YEBO/CHA
8. Ngabe uyaqonda ukuthi ukhulukile ukuhoxa kulesisifundo? YEBO/CHA
   a) noma nini
   b) ngaphandle kokunika izizathu zokuhoxa
9. Uyavuma ukuzibandakanya ngaphandle kwenkokhelo? YEBO/CHA
10. Uyaqonda ukuthi ungase uthole imithi engenalutho i-placebo kulokhu kuhlolwa? YEBO/CHA
11. Uyawuqonda umehluko phakathi kwe-placebo nohlelo lokulashwa ngokwe homoeopathy? YEBO/CHA
12. **Uma uphendule ngo CHA kunoma yimuphi umbuzo ngenhla, uyacelwa ukuba uthole imininingwanwe ngaphambili kokuba usayinde.**

IGAMA LESIGULI: _____

ISISHICILELO: _____

IGAMA LIKAFAKAZI: _____

ISISHICILELO: _____

IGAMA LOMFUNDI OWENZA

UCWANINGO: _____

ISISHICILELO: _____

APPENDIX D1

CHILD ASSENT FORM

NAME OF RESEARCH PROJECT: The efficacy of a homoeopathic complex (*Kalium bromatum* 9CH, *Natrum muriaticum* 9CH, *Selenium* 9CH, *Sulphur* 9CH and *Thuja occidentalis* 9CH) in the treatment of acne vulgaris.

NAME OF SUPERVISOR: Dr Richard Steele BA, HDE, M.Tech.(Hom.)

NAME OF RESEARCH STUDENT: Sameer Ally

Dear Participant

I hope that you are well. Thank you for reading this information letter. I kindly welcome you to take part in this research project. I am studying to be a homoeopathic doctor and to qualify I must complete this research project. In this research project, I am going to test whether a homoeopathic medicine can work well to treat acne (pimples). This may be helpful to you and others like you who have acne.

This research project will take place at the Durban University of Technology Homoeopathic Day Clinic, on weekday afternoons. A qualified homoeopathic doctor will make sure that the treatment goes well.

More information about this research project:

- You can take part in this research project once you have read this letter and signed a permission form. You and your parent/guardian will also need to fill a form that contains all of your personal details (your telephone number, address etc). This will be kept private.
- I will also check that you have the right kind of pimples for this research project.
- Your parent or guardian will also need to read an information letter and sign a consent form giving me permission to treat you.
- You will need to take the medication for 6 weeks. Your parent or guardian will remind you to take your medicine every day.
- Within these 6 weeks you will have to come to the clinic three times. Each time your parent or guardian will come with you.
- The first time you come I am going to ask you and your parent/guardian some questions about your pimples. Then I will look closely at your pimples on your face and count them. This will take about an hour and a half. When this is finished you will then be given the homoeopathic medicine, which are small sweet tasting tablets to take.

- Because this is an experiment to see if the medicine helps your pimples, some people are going to get sugar tablets with medicine added and some are going to get sugar tablets with no medicine added. They will both look and taste the same, so you won't be able to tell which ones you are taking. You and I will only find out which ones you took after the research project is over.
- If you are wearing make-up, you will be asked to clean this off before the pimples are counted.
- You and your parent/guardian will be given instructions on how/when to take the medicine.
- When you come back the second and third time I will ask you questions again about your pimples and count the pimples again too but these appointments will be shorter than the first one (probably about an hour).
- You will need to bring your tablet container with you when you come back the second and third time.
- It is possible at first that your pimples may get a little worse, but this will only be for a short time and the pimples will probably return to the way they were before or maybe even improve. If you are worried about your pimples or any other symptom you may be feeling, please phone me and I will do my best to help you.
- If you got the sugar tablets with no medicine during the six weeks, you will be given the sugar tablets with medicine added, after the research project is over.
- Your parents/guardian do not have to pay for the appointments or medicine.
- If you don't want to carry on with this research project you can stop at any time, even now at the beginning if you want to.

If you have any questions please contact me or my research supervisor at any time.

Sameer Ally *[phone number deleted]*

Dr Richard Steele *[phone number deleted]*

Thank you for your assistance.

Department of Homoeopathy

Durban University of Technology

CONSENT (permission)

When I write my name and sign underneath it means that I have read this letter and I understand what I have read, and I know all I need to know about this research project. I would like to take part in this research project and I know that I can stop taking part in this research project at any time if I want to and I don't have to say why.

PATIENT NAME: _____

SIGNATURE: _____

DATE: _____

PARENT OR LEGAL GUARDIAN ACKNOWLEDGEMENT

I have read the information letter and give my child consent to participate in this research project. I agree to ensure that my child takes a tablet daily for 6 weeks, on waking. I also agree to be present at each of the consultations with my child. I have received a copy of the information letter and understand its contents.

PARENT OR LEGAL GUARDIAN NAME: _____

SIGNATURE: _____

DATE: _____

WITNESS NAME: _____

SIGNATURE: _____

DATE: _____

RESEARCH STUDENT NAME: _____

SIGNATURE: _____

DATE: _____

APPENDIX D2

ISAZISONCWADI ENGANENI

INQIKITHI YOCWANINGO: Amandla lwengxibemithi ye-homoeopathy (*Kalium bromatum* 9CH, *Natrum muriaticum* 9CH, *Selenium* 9CH, *Sulphur* 9CH ne *Thuja occidentalis* 9CH) ekwelapheni izinduna kwisikhumba.

IGAMA LOMHLOLI: UDokotela Richard Steele (BDA HDE) (M. Tech. Hom.)

IGAMA LOMFUNDI OWENZA UCWANINGO: Sameer Ally

Lunga elithandekayo

Ngiyethemba ukuthi uphilile. Siyabonga ngokufunda lencwadi yolwazi. Ngiyakwamukela ukuba ube yingxenya yalolucwaningo. Ngingumfundi ofundela ukuba udokotela wezemvelo ihomoeopathy (Master's Degree in Technology: Homoeopathy) ukuze ngiqede kumele ngenze lolucwaningo, ngizokuhhlola uma kuzosebenza kahle ukuba ulapheke izinduna ngalamakhambi emvelo. Lokhu kungaba usizo kuwe nakwabaningi abanenkinga yezinduna.

Lolucwaningo luzokwenzelwa esikhungweni saseThekwini Durban University of Technology Homoeopathic Day Clinic (umtholampilo) ngezikhathi zantambama phakathi nesonto. Udokotela osewumkantshubomvu kulomkhakha uyoqiniseka ukuthi lokuhlola kuhamba kahle.

Olunye ulwazi oludingekayo mayelona nalolocwaningo:

- Ungalingenela lolucwaningo kuphela uma uzofunda lencwadi bese ugcwalisa ifomu lwemvume yakho. Wena nabazali bakho kuyofanele nigcwalise ifomu elinemininingwane yenu yonke (inombolo yakho kanye nekheli) loku kuyocinwa kuyimfihlo.
- Ngiyobe sengikubheka ukuthi inkinga yezinduna onazo ebusweni izolulungela yini lolucwaningo.
- Abazali noma ababheki bakho kufanele bafunde baphinde bagcwalise lelifomu ukungigunyaza ukuba ngikusize.
- Kudingeka usebenzise lemithi/lemishanguzo amasonto ayisithupha. Abazali bakho abakukhutalele ukukukhumbuza zonke izinsuku.
- Emasontweni ayisithupha kuyofanele ukuba uze kathathu emtholampilo osesikhungweni sethu, ngosuku oza ngalo emtholampilo kuzomele uphelekezelwe abazali bakho.
- Esikhathini sokuqala uma ufiko ngiyokubuza imibuzo mayelana nezinduna zakho wena nabazali bakho noma ababhekeleli bakho. Ngiyobe sengikubuka ngikuhlole nazo izinduna ngizibale, lokho kuyothatha ihora nengxenye salo. Uma sesiqedile ukukuhlola uyobe usinikwa okokwelashwa ngowemvelo okungamaphilisi amancane, anambitheka njengoswidi.

- Ngoba lokhu kuyindlela yokuhlola uma kuzokusiza enkingeni yezinduna, abanye bayathola amaphilisi awushukela okufakwe imithi yokusiza kuwo kanti abanye bayathola amaphilisi awushukela angenawo umuthi. Ayobukeka ngokufana ngeke washo ukuthi yimaphi anomuthi wokwelapha nanga nawo.
- Mina nawe siyobheka emva kocwaningo ukuthi uthathe maphi ngasekugcineni.
- Uma ugcoba okuthile ebusweni uyocelwa ukuba ugeze ngamanzi ukuze kubalwe izinduna onazo ebusweni.
- Uma usubuya esigabeni sesibili noma esesithathu ngiyokubuza imibuzo futhi, mayelana nezinduna, ngizibale kodwa lokhu kuyoba yisikhathi esimfishane esingaba imizuzu engamashumi ayisithupha.
- Kuyadingeka ukuba uphathe isitsha sawo lawa maphilisi uma usubuya okwesibili nokwesithathu.
- Kungenzeka ekuqaleni kokuthatha imithi zivumbuke kakhulu izinduna zakho, kodwa lokhu kuyoba okwesikhashana. Kubuye ube sesimweni esijwayelekile okukanye kube nobungcono. Uma unokukhathazeka nanokungazi okuphawulayo ngesikhumba sakho, thintana nami ngiyokwenza konke okusemandleni ukuba usizakale.
- Uma uthola amaphilisi anoshukela engenawo umuthi phakathi uyowathola nalawa afakwe okokwelapha uma sekuphele ucwaningo.
- Abazali bakho noma ababekeleli bakho ngeke bakhokhiswe lutho ngokubonwa kwakho noma amaphilisi ozowathola.
- Uma ungasazimisele ukuqubeka nalolucwaningo uyoyeka noma inini, ngisho namanje ekuqaleni uma ufuna ukuhoxa.

Uma unanoma yimuphi umbuzo sicela usithinte noma inini

Sameer Ally *[phone number deleted]*

UDokotela Richard Steele *[phone number deleted]*

Siyabonga ngosizo lwakho.

Umnyango weHomoeopathy

Iyunivesi yaseThekwini yobuchwepheshe (Durban University of Technology)

INCWADI YEMVUME (Ukuvumelwa)

Uma ngibala igama lami ngifaka umazisi ngenzansi, kuchaza ukuthi sengifundile ngaqonda ngakhokonke lwalolucwaningo. Ngingakuthokozela ukuba yingxenya yalolucwaningo futhi ngiyazi ukuthi nginelungelo lokuhoxa kulolucwaningo noma ngasiphi isikhathi.

IGAMA LESIGULI: _____

ISISHICILELO: _____

USUKU: _____

UKUVUMA KOMZALI NOMA UMBHEKI WOMNTWANA

Ngiyifundile incwadisaziso futhi ngyamvumela umtwana wami ukuthi azibandakanyise kulolucwaningo. Nginikiwe iphephamfaniswa lalencwadi.

IGAMA LOMZALI NOMA UMBHEKI WOMNTWANA: _____

ISISHICILELO: _____

USUKU: _____

IGAMA LOFAKAZI: _____

ISISHICILELO: _____

USUKU: _____

IGAMA LOMFUNDI OWENZA UCWANINGO: _____

ISISHICILELO: _____

USUKU: _____

APPENDIX E1

DURBAN UNIVERSITY OF TECHNOLOGY HOMOEOPATHIC DAY CLINIC

CONFIDENTIAL PATIENT INFORMATION

RESEARCH PATIENTS ONLY

Please read and complete this form before handing it in.

DATE: _____

Dr/Mr/Mrs/Ms/Master (Please circle)

MALE/FEMALE (Please circle)

SURNAME: _____

FIRST NAME: _____

DATE OF BIRTH: _____

IDENTITY NUMBER: _____

AGE: _____

RACE: _____

MARITAL STATUS: _____

NUMBER OF CHILDREN: _____

OCCUPATION: _____

TELEPHONE

(HOME):_____(WORK):_____

CELLPHONE: _____

POSTAL ADDRESS:

_____

_____

_____

_____

RESIDENTIAL ADDRESS:

_____

_____

_____

APPENDIX E2

DURBAN UNIVERSITY OF TECHNOLOGY (IYUNIVESI YASETHEKWINI YOBUCHWEPHESHE)

HOMOEOPATHIC DAY CLINIC (UMTHOLAMPILO)

ULWAZI LWEZIGULI OLIYIMFIHLO

IZIGULI EZINCWANIGWAYO KUPHELA

Uyacelwa ukuba ufunde bese ugcwalisa lelifomu ngaphambi kokuba ulibuyise.

USUKU: _____

Dkt/Mnu/Nkk/Nksz (ngicela ufake igunquza kuleli elikufanele)

OWESILISA/OWESIFAZANE (ngicela ufake igunquza kuleli elikufanele)

ISIBONGA: _____

IGAMA: _____

USUKU LOKUZALWA: _____

INOMBOLO LOMAZISI: _____

IMINYAKA: _____

UBUHLANGA: _____

ISIMO SOBUDLELWANE SAKHO:_____

ISIBALO SABANTWANA: _____

UMSEBENZI OWENZAYO: _____

UCINGO (LWASEKHAYA):_____(LWASEMSEBENZINI):_____

ISELULA: _____

IKHELI LOKUPOSA:

_____

_____

_____

IKHELI LOMGWAQO:

_____

_____

_____

APPENDIX F

CASE HISTORY

PATIENT DETAILS

DATE AND TIME OF CONSULTATION: _____

PATIENT NUMBER: _____

SEX: _____

AGE: _____

OCCUPATION: _____

MARITAL STATUS: _____

NUMBER OF CHILDREN: _____

ALLERGIES: _____

PRESENTING COMPLAINT

In patient's own words. Concomitant, location, aetiology, modalities, sensations, site, intensity, timing, radiation, duration, history.

PAST MEDICAL HISTORY

What is the current health status of the patient? Are there any serious diseases the patient experienced in the past? Any injuries? Diseases of childhood (e.g. measles, mumps, chickenpox, etc.). Has the patient been admitted to hospital in the past and what for? Has the patient undergone any surgery? Has the patient received any vaccinations? Has the patient been for any x-rays or diagnostic imaging?

DRUG HISTORY

Has the patient taken any medication in the past?

Is the patient currently on any type of medication?

FAMILY HISTORY

The family member's age, current health condition, or cause of death (if applicable).

Mother, father, siblings and grandparents.

Heart conditions or diseases, hypertension, stroke, diabetes mellitus, tuberculosis, asthma, kidney disease, lung disease, arthritis, cancer, neurological disease, headaches, etc.

SOCIAL HISTORY

Conditions of living, social support, diet, smoking and alcohol, exposure to occupational hazards, and history of travelling.

GENERALS

Energy.

Effects of weather, heat or cold on the patient, perspiration, thirst and sleep pattern (also dreams and sleep position).

Libido in males and females, and menses in females.

Appetite (desires, aversions and aggravations), bowel movements and urination.

MENTAL AND EMOTIONAL SYMPTOMS

Introvert or extrovert, fears, emotional traumas, anxiety, irritability, anger, sadness, depression, sensitivity and nervousness.

What makes the patient happy or sad and description of the patient's character.

Does the patient have any delusions?

How is the patient's concentration and memory?

How does the patient feel about company, contradiction and consolation?

SYSTEMS REVIEW

HEAD: Headaches, head injury.

EYES: Vision, glasses or contact lenses, pain, redness, discharge, itching.

EARS: problems in hearing, discharges, tinnitus, vertigo, earache.

NOSE AND PARANASAL SINUSES: Stuffiness, discharge, colds, pain, epistaxis, sinus problems.

MOUTH: Teeth and gum condition. Dry mouth.

THROAT: Sore throat, hoarseness and swallowing difficulties. Glandular swelling and pain in the throat and neck.

RESPIRATORY SYSTEM: Dyspnoea, cough, sputum, asthma, haemoptysis, wheezing.

CARDIOVASCULAR SYSTEM: Chest discomfort and pain, hypertension and palpitations.

GASTROINTESTINAL SYSTEM: Abdominal pain, heartburn, indigestion, reflux, bloating, diarrhoea, stool colour and constipation.

URINARY SYSTEM: Urinary frequency, urgency and burning on urination.

MALE GENITAL SYSTEM: Pain, sores, hernias and sexual problems such as impotence.

FEMALE GENITAL SYSTEM: Menses, sores, discharges and itching. Leucorrhoea.

MUSCULOSKELETAL SYSTEM: Pain and stiffness in the joints, arthritis or gout.

NEUROLOGICAL SYSTEM: Paralysis, weakness, numbness, fainting, pins and needles.

ENDOCRINE SYSTEM: Heat intolerance, cold intolerance and thyroid troubles.

HAEMATOLOGICAL SYSTEM: Bleeding, bruising and anaemia.

SKIN: Rashes, ulcers, itching, sores, conditions of the nails and hair, acne, eczema, psoriasis and warts.

CASE SUMMARY:

Including differential diagnoses, diagnosis, remedy differentials, patient management plan and what the student thinks about the case.

APPENDIX G

PHYSICAL EXAMINATION

(Schultz, 2007:1-6)

THE GENERAL OBSERVATION OF THE PATIENT

Level of consciousness of the patient, apparent state of health, signs of distress, stature and habitus, weight, colour of the skin and lesions of the skin, motor activity, gait, speech, expression of the face, body odours, dressing and state of personal hygiene.

VITAL SIGNS: Blood pressure, pulse rate, respiratory rate, temperature, height and weight.

HAIR: Inspect and palpate.

Amount and distribution of hair, pattern of hair loss, texture and the presence of any foreign particles.

SCALP: Inspect and palpate.

Inflammation, lumps, scaliness and other lesions.

SKULL: Inspect and palpate.

Skull size and contour, deformities, lumps and tenderness.

FACE: Inspect and palpate.

Expression of the face and contours, involuntary movements, symmetry, masses and oedema.

SKIN: Inspect and palpate.

Colour of skin, pigmentation, thickness, texture, lesions and distribution of hair.

EYES: Inspect and palpate.

Eye alignment and position.

Shape, size and equality of the pupils.

Appearance of the cornea and lenses.

Colour, vascular pattern, swellings, nodules and other lesions of the conjunctiva and sclera.

NOSE AND SINUSES: Inspect and palpate.

External: Inflammation, asymmetry and deformity.

Internal: Colour, swelling, bleeding, exudate, perforation, deviation and polyps.

Palpate the sinuses to determine if there is tenderness of the frontal and maxillary sinuses.

MOUTH AND PHARYNX: Inspect and palpate.

Lips: cracks, colour, lumps, ulcers, eruptions, moisture, cracking and other lesions.

Buccal mucosa: Colour, ulcers, pigmentation, nodules and other lesions.

Roof of the mouth: Colour and architecture.

Gums: Swelling, inflammation, bleeding, discolouration and hypertrophy.

Teeth: Abnormalities in shape and position, loose, missing and carious.

Tongue: Colour, size, movements, abnormal smoothness, position, orientation, symmetry, papillae, sides, undersurface and floor of mouth.

Pharynx: Soft palate, uvula, anterior pillars, posterior pillars, tonsils, pharynx. Colour, swelling, exudate, ulceration, lesions, symmetry, tenderness, induration and hypertrophy of the tonsils.

EARS: Inspect and palpate.

Auricle: Shape, symmetry, nodules, deformities, other lesions, colour, discharge, smell and lesions of the skin.

Ear canal and the tympanic membrane: Redness, swelling, foreign bodies, cerumen, discharge, colour, contour and perforations.

NECK: Inspect and palpate.

Neck symmetry, scars, masses, parotid and submandibular glands.

Lymph nodes of the neck: Take note of their size, shape, consistency, mobility, delimitation, tenderness, surface texture and the overlying skin.

Tracheal deviation.

Thyroid gland: Movement, symmetry and contour. Palpate the thyroid gland and note size, shape, consistency, nodules and tenderness. Auscultate the thyroid for bruits.

UPPER LIMBS: Inspect and palpate.

Hand: Shape and symmetry, orientation, nails and nail beds.

Dorsum of the hand, forearm, and upper arm: Colour, lesions, mobility, vascular supply, temperature, hair distribution, inflammation, epitrochlear node.

Palm of the hand, forearm and upper arm: Colour, lesions, mobility, vascular supply, temperature, hair distribution, inflammation, epitrochlear node.

Orientation, mobility and tone of the forearm and upper arm.

AXILLAE: Inspect

Swelling, nodules, other lesions, hair distribution, inflammation and smell.

THORAX: Inspect, palpate and auscultate.

Shape, abnormalities and movement of thorax.

Skin: Colour, pigmentation, hair distribution, texture, inflammation and lesions.

Heart and lungs auscultation.

ABDOMEN: Inspect, auscultate, percuss and palpate.

Inspect the abdomen: size, shape, peristalsis, skin lesions, umbilicus, abdominal contour, symmetry, pulsations and masses.

Auscultate the abdomen: all 4 quadrants – bowel sounds, bruits and friction rubs.

Percuss the abdomen: all 4 quadrants – for tympany and dullness. Percuss liver and spleen.

Palpate: Light palpation in all 4 quadrants – mesenteric lymph nodes, resistance of the muscles, abdominal tenderness and masses. Deep palpation in all 4 quadrants – abdominal masses. Also palpate the liver, spleen, kidneys and aorta.

LOWER LIMBS: Inspect and palpate.

Feet: Shape and symmetry, orientation, nails and nail bed.

Dorsum of foot, lower limb and thigh: Colour, lesions, mobility, vascular supply, temperature, hair distribution, inflammation and popliteal node.

Sole of foot, lower limb and thigh: Colour, lesions, mobility, vascular supply, temperature, hair distribution, inflammation and popliteal node.

Orientation, mobility and tone of the foot, lower limb and thigh.

BACK: Inspect and palpate.

Symmetry, curvature and posture. Take note of any restricted movements.
Auscultate the back.

AXILLAE: Palpate.

Palpation of the following lymph nodes: Central – Deep, distal, anterior and posterior.

Also palpate the supraclavicular and infraclavicular nodes

At the end of the physical exam check for JAUNDICE, ANAEMIA, CYANOSIS, CLUBBING, OEDEMA, LYMPHADENOPATHY and DEHYDRATION.

APPENDIX H

ASSESSMENT SHEET

THE LEEDS COUNTING TECHNIQUE (Burke and Cunliffe, 1984:87-92)

- **Patient number: _____**
- **Consultation: _____**
- **Date: _____**

1. **TOTAL NUMBER OF NON-INFLAMED LESIONS**:
   - **Number of blackheads:**
   - **Number of whiteheads:**
2. **TOTAL NUMBER OF INFLAMED LESIONS:**

a) **Superficial (0.1 cm to 0.5 cm)**

- **Number of papules:**
- **Number of pustules:**

b) **Deep (0.5 cm or larger)**

- **Number of nodules:**
- **Number of cysts:**
- **Number of deep pustules:**

NB: Any intermediate lesions will be counted according to their major component. Non-inflamed lesions on or around the edge of the nose will not be counted.

APPENDIX I1

HOW TO TAKE HOMOEOPATHIC MEDICATION

- Dissolve one tablet under your tongue daily on waking, for 6 weeks.

- Do not touch the tablets with your fingers. Place one tablet into the lid of the plastic container and put the tablet under your tongue. Allow the tablet to dissolve.

- Do not swallow the tablet.

- Wait at least half an hour after taking the tablet before eating, drinking (except water) or brushing teeth.

- Do not store tablets near heat, light, dust and electromagnetic radiation (e.g. television, computers, cellphones, etc.).

- Store tablets in a cool and dry place.

APPENDIX I2

INDLELA YOKUTHATHA IMITHI YAKHO YE HOMOEOPATHY

- Faka iphilisi ngaphansi kolimi lwakho njalo uma uvuka ekuseni, amasonto ayisithupha.

- Ungawathinti amaphilisi ngeminwe yakho. Bheka iphilisi elilodwa esivalweni bese ulifaka ngaphansi kolimi. Liyeke lize liziphelele lona.

- Ungalingwinyi iphilisi

- Linda isikhathi esiyingxenya yehora ngaphambi kokuba udle nokuphuza (ngaphandle uma kwamanzi) noma uxuba.

- Ungawabeki amaphilisi endaweni eshisayo, ekhanyayo, enothile kanye naseduze kwezinto zikagesi (njengo mabonakude, umakhale khukwini kanye nokunye).

- Gcina amaphilisi akho endaweni epholile nengenamswakwame.

APPENDIX J

Raw data

M = Male, **F** = Female, **N-inf.** = number of non-inflamed lesions, **Inf.** = number of inflamed lesions, **Total** = total number of acne lesions

Patient Number	Age	Race	First consultation			Second consultation			Third consultation		
			N-Inf.	Inf.	Total	N-Inf.	Inf.	Total	N-Inf.	Inf.	Total
1M	19	Black	80	72	152	66	77	143	54	62	116
2F	22	Black	79	60	139	91	105	196	102	70	172
3F	21	Indian	51	55	106	58	48	106	35	27	62
4M	27	Black	66	46	112	83	61	144	54	50	104
5F	20	Black	148	164	312	112	112	224	116	94	210
6M	22	Black	96	149	245	61	86	147	55	92	147
8F	24	Black	65	46	111	46	38	84	50	48	98
9M	19	Black	77	91	168	47	78	125	44	81	125
10F	19	Black	79	84	163	64	69	133	47	52	99
11M	23	Black	67	75	142	59	83	142	34	83	117
12F	20	Black	86	81	167	49	71	120	53	79	132
13F	21	Black	100	60	160	67	40	107	58	48	106
14F	21	Black	84	79	163	62	51	113	40	42	82
15M	26	Black	68	79	147	45	70	115	34	62	96
16M	20	Indian	39	44	83	38	35	73	26	34	60
17M	20	Black	38	66	104	36	58	94	35	67	102
18F	23	Black	181	235	416	107	141	248	105	139	244
19F	20	Indian	77	71	148	35	42	77	34	51	85
20F	21	Black	55	83	138	64	71	135	36	52	88
21M	21	Black	64	54	118	43	44	87	37	38	75
23M	18	Indian	45	67	112	35	41	76	36	55	91
24F	20	Black	84	71	155	47	61	108	38	54	92
25F	23	Black	108	78	186	71	57	128	48	47	95
26M	25	Black	41	53	94	32	58	90	32	55	87
27F	21	Black	58	69	127	41	62	103	27	52	79
28F	31	Indian	19	23	42	21	20	41	22	19	41
29F	21	Indian	28	52	80	24	48	72	17	44	61
30M	20	Black	33	38	71	24	44	68	23	36	59
31M	23	Black	29	60	89	25	56	81	19	66	85
33M	19	Black	27	53	80	30	59	89	17	49	66
34F	23	Black	27	32	59	29	25	54	29	22	51
35M	27	White	22	40	62	17	33	50	13	21	34
36F	25	Black	37	49	86	22	39	61	26	38	64
37M	23	Black	25	29	54	18	27	45	20	25	45