

**The efficacy of a complementary formulation
of Folliculinum D6 And Five-Flower Formula™,
in the treatment of menopausal symptoms.**

By:
FATIMA HANSA

Mini-dissertation submitted to the Faculty of Health Sciences at the Durban University of Technology in partial compliance with the requirements for a Master's Degree in Technology: Homoeopathy.

I, Fatima Hansa, declare that this dissertation represents my own work in both conception and execution.

Fatima Hansa

Date

Approved for final submission

Supervisor: _____
Dr. I. Couchman [M.Tech (Hom)]

Date

ACKNOWLEDGEMENTS

I wish to express my sincere gratitude to the following people :

Dr Ingrid Couchman- my supervisor, for her invaluable calmness and untiring efforts and for always providing the most speedy feedback when needed.

Dr Nevorndutt Somaru- for his efficient assistance with the dispensing of medication.

Mrs Clark- for her constant encouragement and advice.

Gugu- for always smiling.

My Dear Parents- I am truly blessed to have your love, guidance and support. Thank you for always believing in me and my endless studies. I love you both.

Sawleha Hansa and Hoosen Padia- my sister and brother, for their immense love and faith. I love having you both in my lives.

Jameel Adams- My darling husband, for not only his great technical knowledge and computer skills, but also for being a pillar of strength, your unending patience, for your amazing understanding and for letting me be me. I love you.

To all the participants who participated in this trial for being an integral part of this dissertation.

ABSTRACT

Introduction

Menopausal symptoms are common causes for women to seek treatment. The severity of symptoms vary from patient to patient and reduces the quality of life for many women. Most women reach menopause between the ages of 45 and 55, some not until 60 and some at an early age in their thirties or forties (Stoppler, 2008).

Aim

This study aimed to offer an alternative form of treatment for women that are experiencing the unpleasant symptoms that are experienced with menopause, since hormone replacement therapy, may have adverse effects in some women (Wang-Cheng, 2007).

This double-blind placebo controlled study investigated the efficacy of a complementary formulation of Folliculinum D6 and Five-Flower Formula™, (Folliculinum D6, Rock Rose, Impatiens, Clematis, Star of Bethlehem, Cherry Plum.) in the treatment of menopausal symptoms in terms of participants' perception of the treatment.

This formula is currently available commercially as an unregistered product trading under the name of Femme Rosa. This formula was developed by Dr Maharaj, and is prepared by Natura®. The formula consists of *Folliculinum* D6 and Five-Flower Formula™.

Methodology

A total of 60 female participants who were going through natural menopause and currently experiencing menopausal symptoms took part in the study. They were randomly assigned according to the randomization sheet drawn up by the supervisor, 29 participants to the treatment group and 31 to the placebo group. The study was conducted over a period of six weeks and participants were required to attend two consultations at the Homoeopathic Day Clinic at the Durban University of Technology. Participants were recruited according to the inclusion criteria set out. During the first consultation the participants completed the Greene Climacteric Scale questionnaire and a concise case history was taken, thereafter each patient was handed two hot flush diaries to be completed one week before treatment and during the sixth week of treatment. Each participant was required to take one tablet every morning and evening for 6 weeks. Six weeks after the first consultation participants attended the second consultation and the Greene Climacteric Scale was completed for the final time and the hot flush diaries collected.

Results

The results of the first questionnaire and hot flush diary were used as a baseline for statistical analyses. As each group consisted of 29 and 31 subjects, non-parametric tests were used for data analysis. All statistical analyses were carried out using SPSS version 15.0.

Conclusion

An improvement was demonstrated in both treatment and placebo groups after treatment yet this improvement was not statistically significant.

The only symptoms that improved in the treatment group were the hot flushes and psychological symptoms however, there were no significant differences between the treatment and placebo group.

It was concluded that the complementary formulation of *Folliculinum D6* and Five-Flower Formula™ was not statistically effective in the treatment of menopausal symptoms in terms of the participants' perception of the treatment.

TABLE OF CONTENTS

ACKNOWLEDGEMENTS	II
ABSTRACT	III
LIST OF TABLES	XI
LIST OF GRAPHS	XII
CHAPTER 1: INTRODUCTION	1
1.1 Introduction	1
1.2 Aim of the Study	1
1.3 Statement of the Objectives	2
1.3.1 The First Objective	2
1.3.2 The Second Objective	2
1.4 Statement of the Hypotheses	3
1.4.1 The First Hypothesis	3
1.4.2 The Second Hypothesis	3
CHAPTER 2: REVIEW OF RELATED LITERATURE	4
2.1 Introduction	4
2.2 Physiology	4
2.2.1 Menstrual Cycle	4

2.2.2 Female Sex Hormones	6
2.2.2.1 The Role of Oestrogens	6
2.2.2.2 The Role of Progesterone	6
2.2.2.3 Follicle Stimulating Hormone and Luteinizing Hormone	7
2.2.3 Changes Occurring At the Menopause	7
2.3 Clinical Picture of Menopause	8
2.3.1 Signs and Symptoms	8
2.3.1.1 Vasomotor	9
2.3.1.2 Psychological	9
2.3.1.3 Genital Changes	9
2.3.1.4 Musculoskeletal	10
2.3.1.5 Cardiovascular Risks	10
2.4 Diagnosis	10
2.5 Treatment	11
2.5.1 Hormone Replacement Therapy	11
2.5.1.1 Types of Hormone Replacement Therapy	11
2.5.1.2 Benefits of HRT	12
2.5.1.3 Side Effects of HRT	13
2.5.1.4 Contraindications of HRT	14
2.5.2 Other Treatment Options	15

2.5.2.1 Nutritional Therapy	15
2.5.2.2 Phytotherapy	16
2.5.3 Homoeopathy	17
2.5.3.1 The General Principles of Homoeopathy	17
2.5.3.2 Complex Prescribing	18
2.5.3.3 Placebo	19
2.6 Constituents of The Complementary Formulation	19
2.6.1 Folliculinum	19
2.6.2 Bach Flowers	22
2.6.3 The Efficacy of Homoeopathic Treatment of Menopausal Symptoms	25
2.7 Measurement Tools	27
2.7.1 The Greene Climacteric Scale (GCS)	27
2.7.2 The Hot Flush Diary	28
2.7.3 The Menopause Rating Scale (MRS)	29
2.8 Data Analysis	29
 CHAPTER THREE : MATERIALS AND METHODS	 30
3.1 Advertising	30
3.2 Selection	30
3.2.1 Selection Criteria	30
3.2.2 Ethical Considerations	31

3.3 Treatment	32
3.3.1 Folliculinum (Femme Rosa)	32
3.3.2 Allocation	32
3.4 Questionnaires	33
3.4.1 The Greene Climacteric Scale (GCS)	33
3.4.2 The Hot Flush Diary	34
3.4.3 The Menopause Rating Scale (MRS)	34
3.5 Assessment	34
3.6 Statistical Analysis	35
CHAPTER FOUR : STATISTICAL ANALYSIS	36
4.1 Introduction	36
4.2 Admissibility Of Data	36
4.3 Statistical Methodology	36
4.4 Results	37
CHAPTER FIVE: DISCUSSION	65
CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS	68
6.1 Conclusion	68
6.2 Difficulties Encountered	68

6.3 Recommendations	69
REFERENCES	71
LIST OF APPENDICES	77

LIST OF TABLES:

Table 4.1 : Wilcoxon signed ranks test to compare change in median number of hot flushes from week 6 to week 1 within the treatment group (n=31).

Table 4.2 : Test Statistics(b,c)

Table 4.3 : Statistics (a)

Table 4.4 : Wilcoxon signed ranks test to compare change in median severity of hot flushes from week 6 to week 1 within the treatment group (n=31).

Table 4.5 : Test Statistics(b,c)

Table 4.6 : Statistics for Severity of Hot Flushes (a)

Table 4.7 : Wilcoxon signed ranks tests to compare change in median scores of Green Climacteric scale from week 6 to week 1 within the treatment group (n=31).

Table 4.8 : Test Statistics(b,c)

Table 4.9 : Report of the median changes in number and severity of hot flushes in the treatment and placebo group from pre to post treatment.

Table 4.10 : Inter-group comparison of change in number and severity of hot flushes between treatment and placebo groups (n=60)

Table 4.11 : Test Statistics(a)

Table 4.12 : Report of the median changes in scores in the treatment and placebo group from pre to post treatment.

Table 4.13 : Inter-group comparison of change in scores between treatment and placebo groups (n=60)

Table 4.14 : Test Statistics(a)

LIST OF GRAPHS:

Figure 4.1 Ages of participants

Figure 4.2 : Bar graph of median number of hot flushes at week 1 and week 6 in the treatment group

Figure 4.3 : Bar graph of median number of hot flushes at week 1 and week 6 in the placebo group

Figure 4.4 : Bar graph of median severity of hot flushes at week 1 and week 6 in the treatment group

Figure 4.5 : Bar graph of median severity of hot flushes at week 1 and week 6 in the placebo group

Figure 4.6 : Bar graph of median scores of Green Climacteric scale at week 1 and week 6 in the treatment group

Figure 4.7 : Bar graph of median scores of Green Climacteric scale at week 1 and week 6 in the placebo group

Figure 4.8 : Change in number of hot flushes over time by treatment group or placebo

Figure 4.9 : Change in severity of hot flushes over time by treatment group or placebo

Figure 4.10 : Change in median scores of Green Climacteric scale over time by treatment group or placebo

CHAPTER ONE : INTRODUCTION

1.1 INTRODUCTION

Menopause is a common cause of discomfort in women, with the average age of onset being between the ages of 45 and 55, whilst some may not develop until 60 and some develop early menopause in their 30's or 40's (Stoppler, 2010).

Menopause is now recognised as a time of decreased hormonal production with associated problems that reduces the quality of life and even quantity for many women (Hacker, Moore, Gambone, 2004).

This study aimed to test the effectiveness of a currently available unregistered product (Femme Rosa) in the treatment of menopause as it has not been clinically tested.

This formula was developed by Dr Ashnie Maharajh, and is prepared by Natura®. The formula consists of *Folliculinum* D6 and Five-Flower Formula™.

1.2 AIM OF THE STUDY

The aim of this clinical trial was to investigate the effectiveness of a complementary formulation of *Folliculinum* D6 and Five-Flower Formula™, in the treatment of menopausal symptoms.

Menopause is a natural phase in the life of every woman but for some, this stage is often associated with many unpleasant symptoms that drive women to seek treatment. It was hoped that an over the counter formulation would assist women by offering a treatment to improve menopausal symptoms, which was safer and convenient without the need of a homoeopathic consultation.

1.3 STATEMENT OF THE OBJECTIVES

1.3.1 The first objective

The first objective was to determine the effectiveness of a complementary formulation of *Folliculinum* D6 and Five-Flower Formula™ in the treatment of menopausal symptoms in terms of the patient's perception using questionnaires.

1.3.2 The second objective

The second objective was to compare the results of the complementary formulation of *Folliculinum* D6 and Five-Flower Formula™ and placebo in the treatment of menopausal symptoms in terms of the patient's perception using questionnaires.

1.4 STATEMENT OF THE HYPOTHESES

All hypotheses are stated in the null form.

1.4.1 The first hypothesis

It is hypothesized that the complementary formulation of Folliculinum D6 and Five-Flower Formula™ will have no effect in the treatment of menopausal symptoms in terms of the patient's perception of treatment.

1.4.2 The second hypothesis

It is hypothesized that there will be no difference between the results of the complementary formulation and the placebo group in the treatment of menopausal symptoms in terms of the patient's perception of treatment.

CHAPTER TWO : REVIEW OF THE RELATED LITERATURE

2.1 DEFINITION AND CLASSIFICATION

Menopause can be defined as the physiologic cessation of menses due to decreasing ovarian function. Perimenopause is usually characterised first by an increase in frequency of menses then by a decrease, although any pattern is possible (Beers, Porter, Jones, Kaplan and Berkwits, 2006).

2.2 PHYSIOLOGY

2.2.1 Menstrual cycle

The average age of menarche is 12.4 years at present (Hacker, *et al.* 2004). The female menstrual cycle lasts more or less 28 days and consists of 3 stages:

The proliferative phase

This is essentially the oestrogen phase occurring before ovulation with the end of menstruation. At this time of the cycle the endometrial lining is desquamated due to menstruation. Oestrogen plasma levels rise due to the growth and amplified secretory activity by the dominant follicle. Glands in the cervical canal

now begin to secrete a thin mucus to assist in the migration of sperm to the uterus (Stanfield and Germann, 2008).

Secretory phase

This is the progestational phase occurring after ovulation in the latter half of the cycle. At this time both progesterone as well as oestrogen is released by the corpus luteum in large amounts (Guyton and Hall, 2005). Progesterone causes the endometrial glands to further enlarge which in turn thickens the endometrium even more, making it favourable for implantation. If implantation does not occur then the corpus luteum degenerates causing plasma levels of oestrogen and progesterone to decline, which now triggers the events of menstruation (Stanfield and Germann, 2008).

Menstruation

Menstruation is essentially the shedding of the uterine lining. Oestrogen and progesterone plasma levels decline rapidly and menstruation then takes place. There is no longer stimulation of the endometrial cells and the endometrium degenerates to approximately 65 per cent of its prior thickness (Stanfield and Germann, 2008). The loss of blood stops within 4 to 7 days after menstruation begins (Guyton and Hall, 2005).

2.2.2 Female sex hormones

2.2.2.1 The role of oestrogens

Oestrogens are responsible for female primary and secondary characteristics. Before puberty oestrogens are secreted in small quantities and subsequent to puberty, under the control of gonadotropic hormones from the anterior pituitary gland, oestrogen is then secreted in large amounts. There is an enlargement of the fallopian tubes, vagina, external genitalia and uterus. Oestrogens are also accountable for the transformation of the vaginal epithelium from cuboidal into stratified epithelium. More importantly oestrogens are responsible for the proliferation of the endometrium and the growth of the endometrial glands (Guyton and Hall, 2005).

2.2.2.2 The role of progesterone

The most significant role of progesterone is to promote secretory-phase uterine conditions. Progesterone also promotes growth of the glandular tissue in the breasts. Progesterone suppresses milk production and uterine contractile activity (Stanfield, Germann, 2008).

2.2.2.3 Follicle stimulating hormone and luteinizing hormone

The hypothalamus releases gonadotropin-releasing hormone (GnRH) which in turn controls the release of follicle stimulating hormone (FSH) and luteinizing hormone (LH) from the anterior pituitary gland. FSH and LH regulate the secretion of oestrogen and progesterone by the ovaries. The above is known as the hypothalamic –pituitary-gonadal axis and is suppressed between the ages of four to ten in a female child. The release of these hormone fluctuate significantly during the various parts of the female menstrual cycle (Hacker, *et al.* 2004).

2.2.3 Changes occurring at menopause

During a normal menstrual cycle, the ovaries produce a sequence of hormones that are regulated by the gonadotropic hormones from the pituitary. Women are born with approximately 1.5 million oocytes and on reaching menarche, they have about four hundred thousand eggs that are possibly responsive. Between menarche and menopause women ovulate about four hundred times and nearly all oocytes are lost. Once all the oocytes have either ovulated or become atretic, the ovaries can no longer respond to pituitary gonadotropins , oestrogen, progesterone and other ovarian follicular hormone diminish. It is the reduction of these hormones that produce unsatisfactory and sometimes harmful physical, psychological and sexual changes in women after menopause (Hacker, *et al.* 2004).

During menopause, even though there is ovarian failure and thus no negative feedback from the ovaries, the ovarian-hypothalamic-pituitary axis remains intact and thus FSH levels increase (Berek, 2007).

The changes in the menstrual cycle are correlated with a shorter follicular phase and in comparison to younger women FSH levels are higher through all the stages of the cycle, whereas there is a significant decrease in the production of oestradiol by the ovaries. Androgens however are continually secreted (Symonds and Symonds, 2004:255-256).

2.3 CLINICAL PICTURE OF MENOPAUSE

2.3.1 Signs and symptoms

The severity of symptoms differ due to the variations in oestradiol during menopause (Symonds and Symonds, 2004:256).

Perimenopausal changes usually begin during a woman's forties. Menses become irregular then are skipped. Symptoms can last from 6 months to about 10 years and vary from nonexistent to severe. Other symptoms that occur are night sweats, irritability, declining libido, weight gain, headaches, mood swings including depression, lack of energy and joint pains (Beers, *et al.* 2006).

2.3.1.1 Vasomotor

The most familiar symptom of menopause is the manifestation of hot flushes which are described as a sudden feeling of heat mainly about the upper torso, head and neck with accompanying perspiration. These attacks may last from a few seconds to a few minutes. The frequency of hot flushes vary from hourly to twenty times a day or more and can be triggered by stress, caffeine, hot weather, alcohol and spicy foods. Insomnia and sleep disruption due to hot flushes accompanied by night sweats are often more distressing to women (Wang-Cheng, 2007).

2.3.1.2 Psychological

Symptoms commonly experienced are a lack of energy, motivation, self-esteem and self-confidence. Other psychological symptoms include mood swings, irritability, forgetfulness, depression, anxiety, feeling of losing control, feeling unable to cope, loss of sex drive, feeling close to tears, vulnerability and lack of concentration (Northrup, 2009).

2.3.1.3 Genital changes

The reduction of ovarian oestrogen results in changes in target organs such as vaginal walls which appear smooth and atrophic, there is a reduction in the size

of the cervix and uterus and cervical mucus production is diminished. The lack of oestrogen results in the skin becoming wrinkled and thin as well as a reduction in pubic, axillary and scalp hair (Symonds and Symonds, 2004:257).

2.3.1.4 Musculoskeletal

The risk of osteoporosis is due to decreased oestrogen (Beers, *et al.* 2006).

The rate of bone loss is approximately 2.5% per year for the first 4 years following menopause producing consequent morbidity in the aged female such as fractures causing immobilisation (Symonds and Symonds, 2004:257).

2.3.1.5 Cardiovascular risks

Generally, the risk of coronary heart disease is lower in women than in men but, following menopause the mortality increases to that of men. One of the factors appears to be a rise in serum cholesterol due to oestrogen depletion in menopause (Symonds and Symonds, 2004), (Mattox, 1998).

2.4 DIAGNOSIS

Diagnosis of menopause is mainly clinical based on the absence of menses for one year (Beers, *et al.* 2006). Menopause can be confirmed by measuring serum FSH levels on several occasions, a level greater than 40 iu/l indicates

menopause. The levels of oestrone, oestradiol and oestriol fluctuate even after menopause therefore measurement of oestrogen levels is not helpful (Oats and Abraham, 2005).

Before administering any treatment, a family and medical history should be recorded and a physical examination performed. Bone density may also be measured. A mammography may also be performed. The above information helps assess the risk of postmenopausal problems (Beers, Fletcher, Jones, Porter, Berkwits and Kaplan, 2003).

2.5 TREATMENT

The majority of treatment is symptomatic along with lifestyle changes.

Recommendations for hot flushes are to avoid triggers and dress accordingly.

Regular exercise, avoiding stress, relaxation techniques may help with sleeping problems and reduce irritability as well as vasomotor symptoms. Vaginal lubricants and moisturizers can also be used. Hormone replacement therapy is commonly prescribed (Beers, *et al.* 2006:2081).

2.5.1 Hormone Replacement Therapy

The treatment of menopause with oestrogen provides many with symptomatic relief, although research has shown significant unfavourable effects in a

marginal number of women. HRT can contain oestrogen on its own or it can be a combination of oestrogen and progesterone (Symonds and Symonds, 2004:257-258).

2.5.1.1 Types of Hormone Replacement Therapy

There is a wide range of Hormone Replacement Therapy (HRT) products on the market, including the following:

- Oral preparations that are absorbed through the gut which are generally well tolerated. These contain conjugated equine oestrogens and estradiol.
- Transdermal applications that are absorbed through the skin such as patches, gels, nasal sprays and vaginal formulations that may assist with vaginal dryness, urinary infections and incontinence.
- Implants that are inserted under the skin with a local anesthetic releases hormones into the subcutaneous fatty tissue which then reaches blood circulation (Sturdee, 2003).

2.5.1.2 Benefits of HRT

The primary benefit of HRT usage is symptomatic relief and as a preventative to osteoporosis. Hormone therapy is found to be very effective in the following :

- Treatment of hot flushes

- Improving sexual function and lowering the risk of infections by preventing dryness and thinning of the vaginal and urinary tract tissues
- Maintains the elasticity of the skin and prevents dryness
- Decelerates the process of osteoporosis

(Beers, *et al.* 2003).

2.5.1.3 Side effects of HRT

Complications can comprise of a rise in endometrial, breast and ovarian cancers. The threat of these cancers rise the longer the patient is taking HRT. The risk of breast cancer rises after four years of treatment with hormone therapy and during the first year, the risk of developing gallstones increases (Beers, *et al.* 2003).

Venous thrombosis and hypertension are other possible risks while on HRT (Symonds and Symonds, 2004:258-259).

The Heart and Oestrogen/Progestin Replacement Study (HERS) was a randomised controlled study of hormone therapy in over 2,700 women with established coronary heart disease. This study concluded that hormone therapy did not benefit in further prevention of coronary heart disease in women who were already afflicted (Berek,2007:66).

The Women's Health Initiative (WHI) was a randomised controlled study of combined oestrogen and progestin hormone therapy for prevention of disease in postmenopausal women. The combined oestrogen-progestin group included approximately 16,000 participants without pre-existing coronary heart disease. The findings were that 29% of the treatment group developed primary coronary heart disease and the risk of breast cancer increased, but the treatment did offer protection against colon cancer and hip fractures (Berek, 2007:66).

2.5.1.4 Contraindications of HRT

HRT is contraindicated in women with liver disease, breast cancer / benign breast disease, history of thrombosis, high blood pressure, fibroids, migraines and endometriosis. HRT is also contraindicated in gall bladder disease, ischaemic heart disease, hyperlipidaemia and diabetes. HRT has an effect on the whole circulatory system. It is necessary that women weigh up the positive and negative effects of HRT, especially when there are plenty of alternatives for coping with symptoms (Glenville 1998:20-26), (Symonds and Symonds, 2004:258).

2.5.2 Other treatment options

2.5.2.1 Nutritional therapy

According to Stengler and Stengler (2003) many nutrients are used to assist in alleviating menopausal symptoms :

Calcium-important for bone health and to protect against osteoporosis and is also indicated for muscle aches and cramps, insomnia, joint pain and high blood pressure.

Magnesium-equally important for bone health and indicated in osteoporosis, muscle cramps and spasms, fibromyalgia, fatigue, insomnia, anxiety, irritability and heart disease.

Vitamin E –found to be effective in reducing hot flushes in some women. Also indicated in heart disease, arthritis and breast tenderness.

Vitamin C- protects against heart disease, assists with immune function and protects against cell damage.

B vitamins- often depleted in times of stress and poor lifestyle choices such as excessive alcohol consumption, smoking and too much caffeine. Intake of this vitamin will assist with stress, anxiety, nervousness.

2.5.2.3 Phytotherapy

Angelica sinensis (*Dong Quai*) has been used for many years as a tonic and spice in Chinese medicine and is a popular herb that is used through the menopausal period (Bloch and Lewis, 2003). The treatment of menopausal symptoms such as hot flushes using *Angelica sinensis* seems to be ill advised as no benefits were found through clinical trials although it can be of use in a menopause tonic (Mills and Bone, 2007).

Vitex agnus-castus (*chaste tree*) is used in the treatment of menopausal symptoms as well as for HRT withdrawal. *Vitex agnus-castus* acts as a prolactin inhibitor, dopamine antagonist, galactagogue and is indirectly progestogenic (Mills and Bone, 2007).

Dioscorea Villosa (*Wild yam*) as a cream is absorbed through the skin and has been known to relieve hot flushes, mild joint and muscle aches and vaginal dryness (Bloch and Lewis, 2003). It's key actions are anti-inflammatory, oestrogenic and antispasmodic. Excessive dosage can cause irritation within the digestive tract (Chevallier, 2007).

Cimicifuga racemosa (*Black cohosh*) has oestrogenic effects that assist with many of the symptoms of menopause as well as symptoms stemming from ovarian insufficiency or dysfunction (Mills, Bone, 2007). Recent research has shown incidents of autoimmune hepatitis in some women (Nazario, 2003).

2.5.3 Homoeopathy

2.5.3.1 The general principles of homoeopathy

Hahnemann was the founder of homoeopathy which is a holistic form of treatment that takes the entire patient into account. It considers all the signs and symptoms that a patient is experiencing including mental and emotional states. Essentially there are three main principles in homoeopathy :

- The first and foremost being “ The Law of Similars”, likes cure likes.
This simply means that the remedy for a specific illness is the same substance that can produce a similar symptom picture and sequence of the illness (Kayne, 1997).
- The second principle is that of “Minimal Dose”.
Remedies are made according to standardized pharmaceutical methods and guidelines. Remedies are diluted and made into a potency which can now make even a toxic substance safe to use (Kayne, 1997).
- The third principle is making use of a “Single Remedy”.

Hahnemann believed that a person could not suffer from more than one illness at a time, and his final principle was to use a single remedy instead of multiple prescribing. This is known as the classical approach in homoeopathy (Kayne, 1997).

2.5.3.2 Complex prescribing

Classical homoeopaths follow Hahnemann's principles of prescribing only a single remedy at a time to a patient. A few remedies can be combined and used successfully as a complex. Use of a complex increases the chance of a correct prescription and may yield better results and is used mainly when the prescriber is unsure as to which remedy best fits the pattern of illness. Another reason for the use of a complex is to treat more than one complaint at the same time and lastly it is used out of convenience. The unfortunate part of this type of prescription is that the homoeopath will not be sure as to which single remedy in the complex cured the patient (Kayne, 1997).

Complex prescribing for menopause will assist a number of women who cannot make the time for a consultation.

2.5.3.3 Placebo

During clinical drug trials, test subjects are divided into treatment and placebo groups where the treatment groups are given active medication and the rest are given placebos which imply inactive medication. A placebo is usually a sugar pill that replaces genuine treatment and the test subjects do not know whether they are receiving the active drug or a placebo.

Research has shown that the expectations of participants can actually influence their healing processes and since they expect their medication to work, the placebo may have a therapeutic effect. Therefore during a clinical trial, active medication is tested against a control group receiving a placebo to make sure that any positive results take into account this placebo response and for a drug to be deemed effective the positive results shown by the treatment group must far outweigh the placebo group (Lockie, 2006).

2.6 CONSTITUENTS OF THE COMPLEMENTARY FORMULATION

2.6.1 Folliculinum

Folliculinum is derived from folliculin (also known as oestrone), which is a natural hormone secreted by the ovaries. Biologically, the smallest quantity of folliculin necessary to produce vaginal signs of oestrus (heightened sexual

arousal) in a castrated female rat is 140g by subcutaneous injection at 3 hourly intervals (Allen and Doisy's test). It is a white crystalline substance, insoluble in water. The first 3 attenuations are made by trituration, the base unit being 140g (Julian, 1979).

Folliculinum is primarily a female remedy. The clinical picture of *Folliculinum* is as follows:

Mental symptoms that indicate this remedy are panic attacks, mood swings that alternate between aggression and depression, hypersensitivity to noise, heat and contact, depression, anxiety, hyperactivity and forgetfulness (Assilem, 1991).

Other mental symptoms include pre-menstrual migraines, sexual hyper-excitability, instability and anguish which is worse at night (Julian, 1979).

General symptoms include hypersensitivity to heat and contact, need for fresh air, weight gain without excessive eating, cycle irregularities, hot flushes, night sweats, dizziness, fainting, changes in libido and water retention (Assilem, 1991).

Local symptoms are swollen breasts that are worse for touch, bloody discharge or spotting, vaginal dryness, drawing and burning pains especially in the ovaries (Assilem, 1991).

Indications:

- Menopause
- Premenstrual symptoms
- Candida Albicans
- Ovarian cysts
- Polycystic Ovarian Syndrome
- Menstrual problems
- Cardiovascular disease
- Raynaud's disease
- Eating disorders
- Post-natal problems
- Myalgic Encephalomyelitis
- Fibroids
- History of abuse, whether sexual, physical or psychological

(Assilem 1991)

The Materia Medica of *Folliculinum* covers a wide range of physical and mental symptoms regarding menopause such as :

- Cycle irregularities
- Flooding
- Hot flushes

- Hyperactive
- Night sweats
- Air hunger
- Dizziness and faintness
- Abdominal heaviness
- Fibroids
- Folliculaemia
- Vaginal dryness
- Slow movement and spacey thinking
- Hypersensitive to noise, heat and touch

(Assilem, 1991)

2.6.2 Bach flowers

Bach was a physician and bacteriologist who discovered the use of flower remedies to treat the most common negative moods that people experience (Kayne, 1997).

Bach Flower remedies can be used on anyone and their safety is highlighted in combining them with other medication (Chancellor, 1995).

The Bach Flower Remedies are intended to treat the person as an individual for the temperament and personality. They are not a treatment for physical complaints, but because our body responds either positively or negatively to the way we think and feel in ourselves, by helping us feel more positive, our body

has a chance to respond equally positively, and thus re-establish a general betterment in our being as a whole (Howard, 2005:3).

“The esoteric view is that most disease of modern mankind originate not so much at the mental level as at the emotional level, the plane of unconscious emotions and subjective reactions that are either blocked or over-stimulated” (Scheffer, 1990:24).

The Bach Flower remedies included in this formulation consist of Rock Rose, Impatiens, Clematis, Star of Bethlehem and Cherry Plum.

Rock rose is used in individuals who are in a state of terror, panic and extreme fright- whether the person is in good health or not. People who are suffering from this state of mind are usually in a serious condition, It is also useful when the situation of the patient is so grave that it affects those around him (Chancellor, 1995:162).

Many women experiencing menopause go through a feeling of being unable to cope and fear of losing control.

Impatiens is indicated in people who feel impatient, irritable, extreme mental tension and for those who are quick in mind and action. The mental tension often manifests as muscular tension and pain. Impatiens is an effective remedy for all manifestations of pain caused by tension such as sudden cramp, an agonizing pain, or other spastic conditions (Chancellor, 1995: 121).

It is common that women experiencing menopause also experience severe mood swings and irritability that this flower may be able to subdue.

Clematis is used in individuals who experience a sense of indifference, dreaminess, inattention and unconsciousness. The people needing Clematis have poor memories, they avoid difficulties or unpleasantness by allowing their attention to wander and by withdrawing (Chancellor, 1995:76).

Lack of concentration is a common symptom in women experiencing menopause.

Star of Bethlehem is often indicated after the effect of mental or physical shock.

This remedy is one of the five indicated in Rescue Remedy and its function is to neutralize shock in any form. Dr Bach called this remedy “The comforter and soother of pains and sorrows” (Chancellor, 1995:179).

Women going through menopause do have a sense of vulnerability, insecurity and depression that can be helped by the Bach Flower remedies.

Cherry Plum is a remedy for the desperation and deep depression of those on the verge of a nervous breakdown. The distress becomes so great, that they fear the mind will give way under strain. They fear that they will lose control of their thoughts or actions, and be impelled to do something dreadful or to commit

an act which in a happier time they would not consider for a moment
(Chancellor, 1995:61).

Menopausal women commonly experience the feeling of losing control and anxiety therefore the inclusion of this flower remedy.

2.6.3 The Efficacy Of Homoeopathic Treatment Of Menopausal Symptoms

Domleo (2002) conducted a study to determine the effectiveness of *Folliculinum* 30CH in the treatment of menopausal symptoms in terms of the participants' perception using questionnaires. There was no overall improvement in the participants who received treatment compared to those that received placebo. The only symptoms that improved within the treatment group were the psychological symptoms in the Greene Climacteric scale and the number of hot flushes. These two variables are the most common reason for treatment requests during menopause and have the most negative impact on quality of life as they cause insomnia and psychological symptoms.

A study conducted by Hagen (1995) was done to determine the effectiveness of the homoeopathic simillimum on the menopausal syndrome in terms of the patient's perception of treatment using the Psychological General Well-Being Index (PGWBI), the patient's perception of treatment and hot flush questionnaire. The study included 30 participants, 15 of which were placed in the placebo group and the remaining 15 in the treatment group. The treatment

shows a 33% greater improvement in anxiety, depression, well-being and vitality than the placebo group according to the scores of the PGWBI questionnaires before and after treatment. When comparing scores of the Participants Perception of Treatment and Hot Flush Questionnaire before and after treatment the treatment group showed a 40% greater improvement over the placebo group, this included significant improvement in vasomotor, emotional and other symptoms.

Macquet-Maurel (2003) conducted a study to determine the efficacy of *Dioscorea villosa* cream in the treatment of menopausal symptoms in terms of subjective data. Thirty female subjects were selected to participate in the study, of which 15 were placed in the treatment group and 15 in the placebo group. Inter group comparison procedures revealed no difference between treatment and placebo groups after treatment, however intra group comparison displayed significant improvement in the depression, anxiety, somatic and sexual symptom scores within the treatment group. Similar improvements were observed in the placebo group that could be due to the common base ingredients that were present in both treatment and placebo creams or due to the placebo effect. It was also concluded that this trial showed no difference between the efficacy of this cream in terms of subjective data given by the participants.

Mc Teer (2003) conducted a study to determine the efficacy of *Dioscorea villosa* cream in the treatment of menopausal symptoms in terms of subjective and

objective data. The study included 30 participants, 15 of which were placed in the treatment group and the remaining 15 in the placebo group. The ProgestoNat Cream® was shown to be effective in treating vasomotor symptoms of menopausal syndrome. This is valuable in that these symptoms have the most negative impact on quality of life. According to objective data the ProgestoNat® cream is an ineffective form of therapy.

Kirtland (1994) conducted a study to evaluate the effect of *Folliculinum* 15CH on participants experiencing premenstrual tension. A sample of 31 participants were used, 16 of which were treated with homoeopathic medication and the remaining 15 were placed in the placebo group. It was noted that in the treatment group 89% of the participants improved while in the placebo group only 7% showed improvement.

2.7 MEASUREMENT TOOLS

2.7.1 The Greene Climacteric Scale (GCS)

The scale is intended specifically to be a brief and standard measure of core climacteric symptoms or complaints to be used for comparative and replicative purposes. Depending on the purpose of the research this scale can be supplemented by other measures assessing characteristics of climacteric women. These might include measures to assess some of the symptoms

included in the scale in greater depth, such as vasomotor symptoms. The Greene Climacteric Scale measures a total of 21 symptoms (Appendix I). Each symptom is rated by the patient according to its current severity using a four-point rating scale: not at all (0); a little (1); quite a bit (2) and extremely (3). The symptoms are related to psychological (anxiety and depression), somatic and vasomotor functions in the climacteric (Chatta, R., Kulkarni, R., Nagarathna, R., Nagendra, H.R. 2008).

2.7.2 The Hot Flush Diary

The hot flush diaries (Appendix J) are a subjective method of assessment that is uncomplicated and simple for participants to record their daily hot flush activity. The hot flush diary will be used to record the total number of hot flushes per day as well as their severity that is mild, moderate, severe, very severe. Self-report diaries have been established as a valid method to obtain subjective data such as symptoms and perceptions reported by the patient. The method of these self-report diaries produces legitimate and dependable information and can sometimes be even more accurate than objective methods (Sloan, J.A., Loprinzi, C.L., Novotny, P.J., Barton, B.I., Lavoisier, B.I., Windschitl, H. 2001).
(Appendix J)

2.7.3 The Menopause Rating Scale (MRS)

The Menopause Rating Scale (MRS) (Appendix H) was initially developed in the early 1990s as a modern tool for the assessment of menopausal complaints by rating a profile of symptoms in a standardized manner. The scale is laid out to provide levels of severity of symptoms ranging from 0 (no complaints) to 4 (very severe) and can easily be filled out subjectively by the patient (Heinemann, L., DoMinh, T., Strelow, F., Gerbsch, S., Schnitker, J., Schneider, H. 2003).

In practice it proves excellent applicability and good reliability and could serve as an adequate diagnostic instrument for menopausal quality of life (Heinemann, *et al.* 2003). (Appendix H)

2.7.4 Data Analysis

SPSS version 15.0 (SPSS Inc., Chicago) was used to analyse the data. A p value <0.05 was considered as statistically significant. Non parametric statistical testing was performed on the parameters due to the significant skewing of the data. Paired Wilcoxon signed ranks tests were used to compare changes from pre to post treatment intra-group. Mann-Whitney tests were used to compare changes from pre to post inter-group.

CHAPTER THREE : MATERIALS AND METHODS

3.1 ADVERTISING

Participants were recruited through advertisements that were placed on notice boards at the Durban University of Technology and other tertiary institutions, pharmacies, health shops and libraries. A newspaper article about this study was published in local newspapers as well as discussions on the local radio stations conducted (Appendix A).

3.2 SELECTION

3.2.1 Selection criteria

Generally, menopause is diagnosed clinically (Beers, *et al.* 2006). Participants were diagnosed by the researcher, therefore the inclusion criteria were as follows :

Inclusion criteria :

- Perimenopausal women, menopausal women or women experiencing menopausal symptoms for at least 3 months.
- Menopause Rating Scale score of 2 or more in at least 3 items.

- Women experiencing natural menopause.
- Women who have undergone a partial hysterectomy (ovaries remaining).
- Women NOT on any other forms of naturopathic/homoeopathic/allopathic treatment for menopausal symptoms 3 weeks before their commencement in the trial.

Exclusion criteria

- Women who have undergone a complete hysterectomy (ovaries removed)
- Women on current hormonal therapy.

This study was a double blind placebo-controlled study that included 60 participants. Thirty one of which were placed in a treatment group and the remaining 29 placed in a placebo group. The participants were randomly divided, by means of a randomisation sheet drawn up by the lab technician, between treatment and placebo groups.

Before selection, the participants were given the subject information letter (Appendix C) to read, and, if they met the criteria and were willing to participate, they were given an informed consent form to sign (Appendix D).

3.2.3 Ethical considerations

The nature and design of the study was explained to each participant. Those that agreed to participate in the study then signed an informed consent form (Appendix D).

3.3 TREATMENT

3.3.1 Folliculinum (Femme Rosa)

Manufacturing Process Of Tablets

In an email from Dr Uwe Hohl, the head of the dispensing laboratory, on 17th June 2009, the tablets were manufactured by the Natura® Laboratory in Pretoria and were medicated according to a laid down procedure as per German homoeopathic pharmacopoeia (Appendix F).

The tablets are prepared according to method 9 of the German homoeopathic pharmacopoeia. The active tablets as well as the placebo are each made from 25mg sugar of milk (British Homoeopathic Association, 1991).

The placebo tablets looked and tasted identical to the medicated tablets.

The lab technician bottled the tablets, and labeled the bottles of tablets according to the randomization sheet, which he then dispensed to each participant.

3.3.2 Allocation

In order for the study to be double blind, the supervisor randomly chose which of the containers labelled from number 1-60 would contain the treatment tablets and which would contain the placebo. The lab technician randomly dispensed the containers to the participants as they presented for treatment.

Participants in both groups were allocated one container of 84 tablets containing either the treatment tablets or placebo. They were instructed to take one tablet every morning and evening for 6 weeks.

The participants were given instruction pamphlets (Appendix G) on how to take homoeopathic medication.

3.4 QUESTIONNAIRES

3.4.1 The Greene Climacteric Scale (GCS)

Participants were required to complete the GCS prior to treatment for the researcher to obtain a baseline of the menopausal symptoms being experienced. Upon completion of treatment participants once again completed the GCS. The information was then collaborated and used to statistically compare the results before and after treatment, as well as comparing results between the placebo and treatment groups (Appendix I).

3.4.2 The Hot Flush Diary

The hot flush diary was completed everyday for a week before treatment to provide a baseline of the number and severity of hot flushes experienced by each participant. The diaries were again filled out everyday during the last week of treatment and the total results obtained, statistically examined and compared to prove the effectiveness of the treatment (Appendix J).

3.4.3 The Menopause Rating Scale (MRS)

The MRS was included in the inclusion criteria of this study. Participants had to be experiencing a score of 2 or more in 3 or more items on the scale in order for them to be accepted as experiencing true menopausal symptoms (Appendix H).

3.5 ASSESSMENT

Consultation one :

At the first consultation the researcher assessed each patient according to the inclusion and exclusion criteria to determine if they were suitable for the study. If these criteria were met then a full medical history (Appendix E) was taken with emphasis on the gynaecological history and a physical exam was performed. Each patient was required to complete the Menopause Rating Scale to confirm their menopausal status. The patient then completed an informed consent form (Appendix D). Participants were required to fill out a hot flush diary (Appendix J) one week prior to commencing treatment in order for a baseline to be obtained as well as complete the GCS (Appendix I). Medication was dispensed according to the randomisation chart by the lab technician.

Consultation two :

Participants were called to attend the second consultation after 6 weeks of treatment. At the second consultation they handed in their hot flush diary and completed the GCS.

3.6 STATISTICAL ANALYSIS

The severity of score symptoms of each questionnaire and the total number of hot flushes as well as severity were tabulated at each consultation for statistical analysis.

Ten participants dropped out of the study therefore statistical analysis was on the basis of 60 results.

The variables of the study used were measured using the participants' perception with regards to the GCS and Hot Flush Diary.

CHAPTER FOUR : STATISTICAL ANALYSIS

4.1 INTRODUCTION

This chapter displays the subjective statistical results acquired from the Greene Climacteric Scale questionnaire as well as the results from the hot flush diary.

4.2 ADMISSIBILITY OF DATA

Only the data acquired in this study were used for the statistical analyses displayed in this chapter.

4.3 STATISTICAL METHODOLOGY

A p value <0.05 was considered as statistically significant. Non parametric statistical testing was performed on the parameters due to the significant skewing of the data.

Paired Wilcoxon signed ranks tests were used to compare changes from pre to post treatment intra-group. Mann-Whitney tests were used to compare changes from pre to post inter-group.

4.4 RESULTS

Sixty participants were randomized into two groups. There were 31 participants in the treatment group and 29 in the placebo group. Ages of participants ranged from 30 to 69. The most common age of participants was 50.

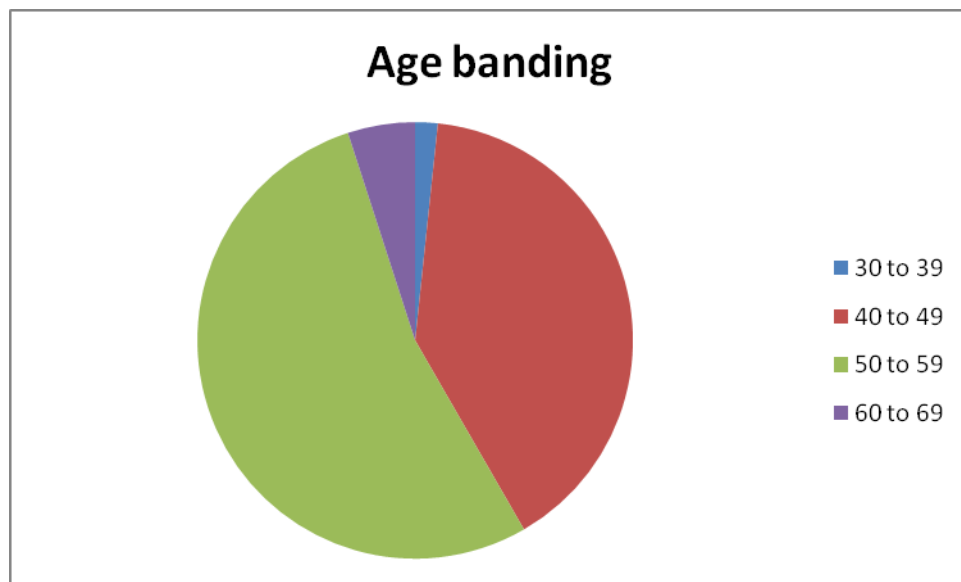


Figure 4.1 Ages of participants

The First Hypothesis

The null hypothesis is that the complementary formulation of Folliculinum D6 and Five-Flower Formula™ will have no effect in the treatment of menopausal symptoms in terms of the participants' perception of treatment.

Intra-group analysis was done on the treatment group only for this hypothesis. The findings of the questionnaires post treatment were compared with the baseline outcomes pre treatment.

The Hot Flush Diary

Number of hot flushes:

Median number of hot flushes per day in the first week (7 days) of the study pre treatment was calculated for each respondent in the treatment group. The median number of hot flushes per day in the first week was 10, with an interquartile range from 5 to 13 and a range from 1 to 5.

At week 6 (post treatment) the median number of hot flushes in the treatment group had reduced to 2 flushes per day with an interquartile range of 1 to 5 and a range from 0 to 20. This decrease was highly statistically significant ($p < 0.001$). Table 4.1 shows that in 27 of the 31 participants there was a decrease in the median number of hot flushes from week 1 to week 6, and in 3 participants there was an increase and in one participant there was no change.

Table 4.1 : Wilcoxon signed ranks test to compare change in median number of hot flushes from week 6 to week 1 within the treatment group (n=31).

		N	Mean Rank	Sum of Ranks
Median number hot flushes week 6 - Median number hot flushes week 1	Negative Ranks	27(a)	15.56	420.00
	Positive Ranks	3(b)	15.00	45.00
	Ties	1(c)		
	Total	31		

a Median number hot flushes week 6 < Median number hot flushes week 1

b Median number hot flushes week 6 > Median number hot flushes week 1

c Median number hot flushes week 6 = Median number hot flushes week 1
group = Treatment group

Table 4.2 : Test Statistics(b,c)

	Median number hot flushes week 2 - Median number hot flushes week 1
Z	-3.862(a)
Asymp. Sig. (2-tailed)	<0.001

a Based on positive ranks.

b Wilcoxon Signed Ranks Test

group = Treatment group

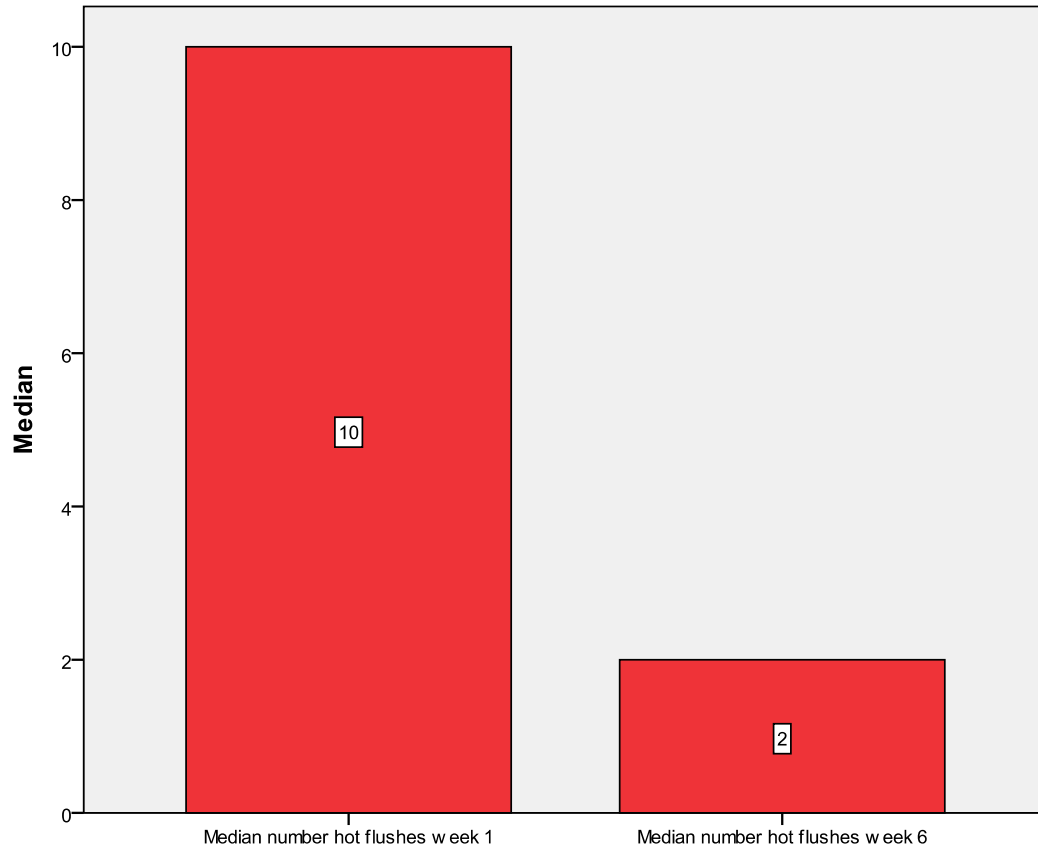


Figure 4.2 : Bar graph of median number of hot flushes at week 1 and week 6 in the treatment group

Number of hot flushes:

group = Placebo

Table 4.3: Statistics^a

		Median number hot flushes week 1	Median number hot flushes week 6
N	Valid	29	29
	Missing	0	0
Median		5.00	1.00
Minimum		1	0
Maximum		24	15

a. group = Placebo

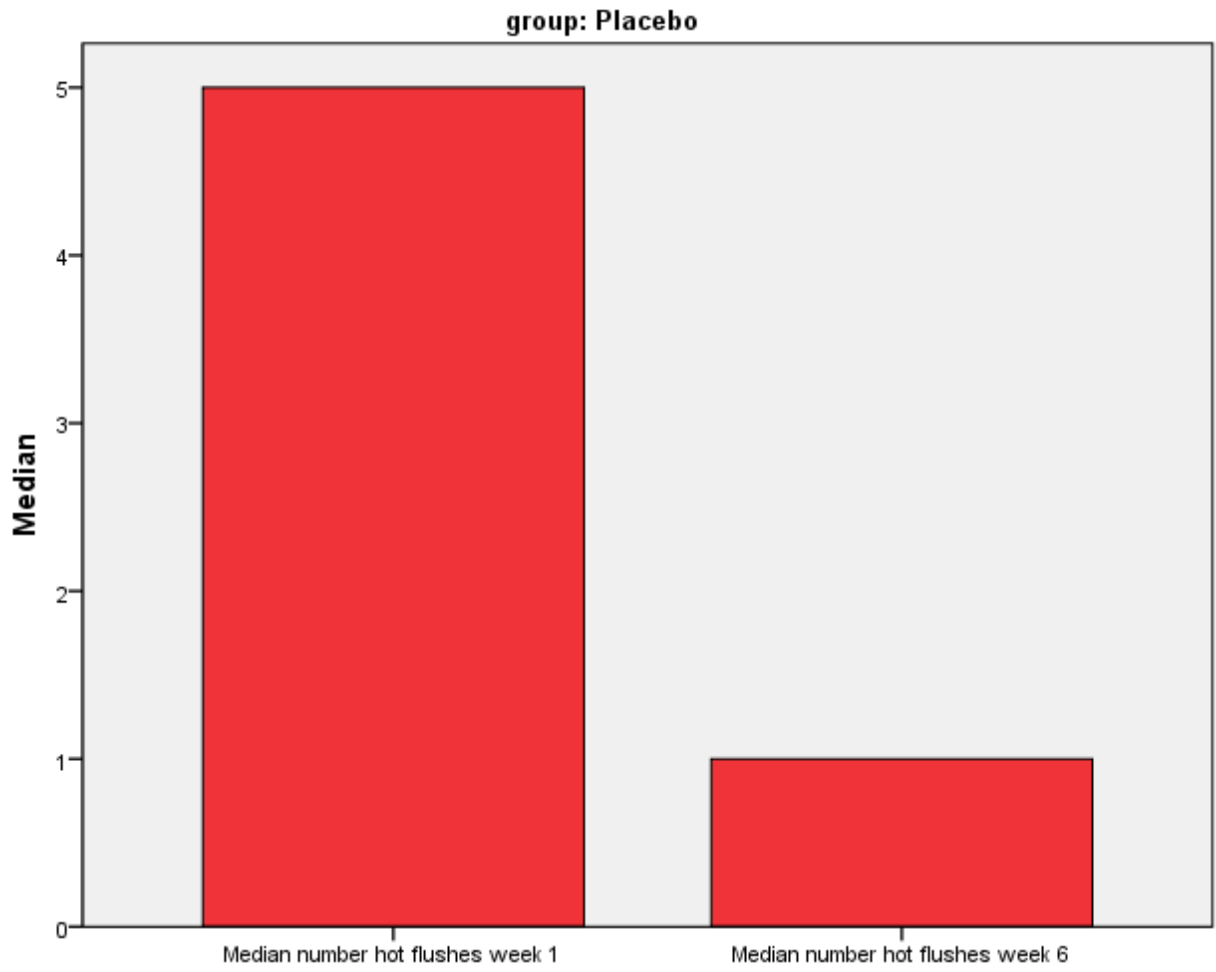


Figure 4.3 : Bar graph of median number of hot flushes at week 1 and week 6 in the placebo group

Severity of hot flushes:

The median severity was 4 (very severe) in the treatment group at week 1 (interquartile range from 2 (moderate) to 4 (very severe)). After treatment, at week 6 the median severity had decreased to 1 (mild) with an interquartile range of 1 (mild) to 2 (moderate). This represented a highly significant decrease ($p < 0.001$). Table 4.4 shows that in 26 of the 31 cases, the severity decreased and in 2 it increased while in 3 it stayed the same.

Table 4.4 : Wilcoxon signed ranks test to compare change in median severity of hot flushes from week 6 to week 1 within the treatment group (n=31).

		N	Mean Rank	Sum of Ranks
Median severity 6 -	Negative Ranks	26(a)	15.23	396.00
Median severity 1	Positive Ranks	2(b)	5.00	10.00
	Ties	3(c)		
	Total	31		

a Median severity 6 < Median severity 1

b Median severity 6 > Median severity 1

c Median severity 6 = Median severity 1

group = Treatment group

Table 4.5 : Test Statistics(b,c)

	Median severity 6 - Median severity 1
Z	-4.444(a)
Asymp. Sig. (2-tailed)	<0.001

a Based on positive ranks.

b Wilcoxon Signed Ranks Test

group = Treatment group

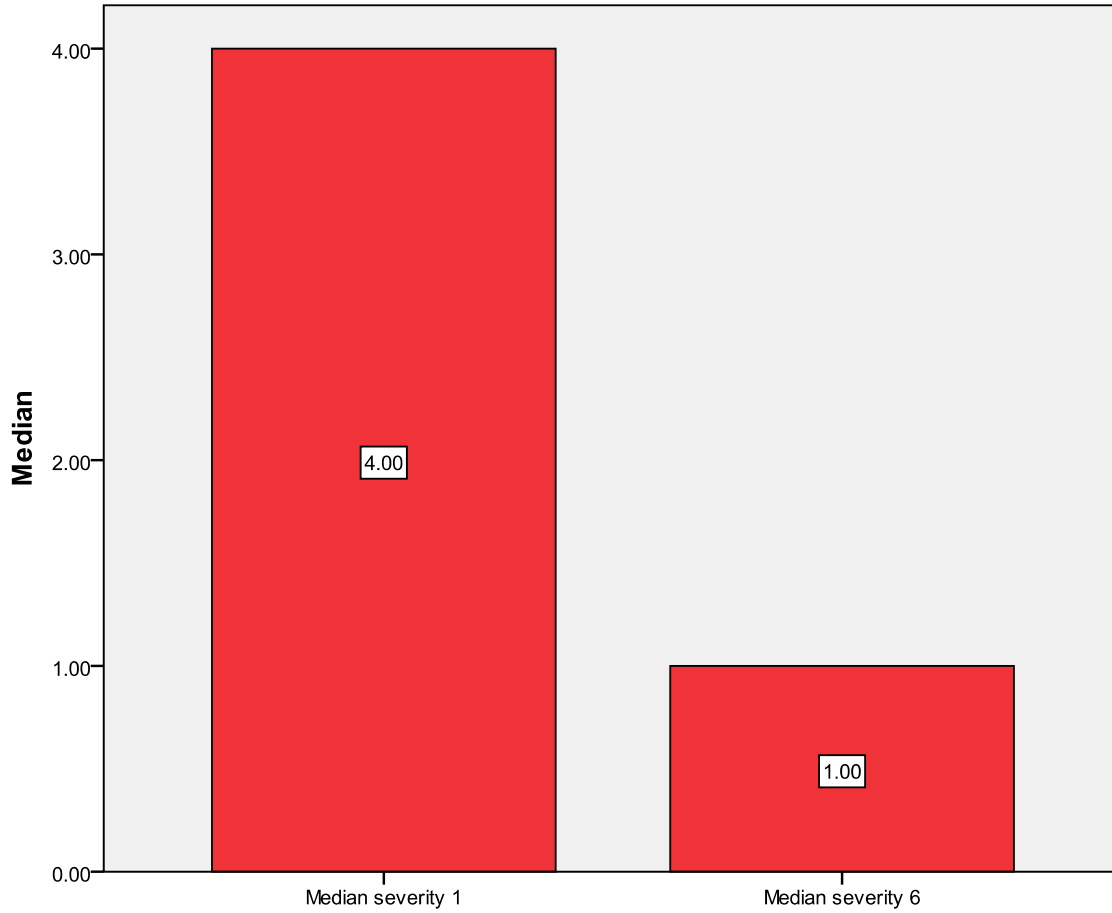


Figure 4.4 : Bar graph of median severity of hot flushes at week 1 and week 6 in the treatment group

Severity of hot flushes:

group = Placebo

Table 4.6 : Statistics for severity of hot flushes (a)

		Median severity 1	Median severity 6
N	Valid	29	29
	Missing	0	0
Median		4.0000	1.0000
Minimum		2.00	.00
Maximum		4.00	4.00

a. group = Placebo

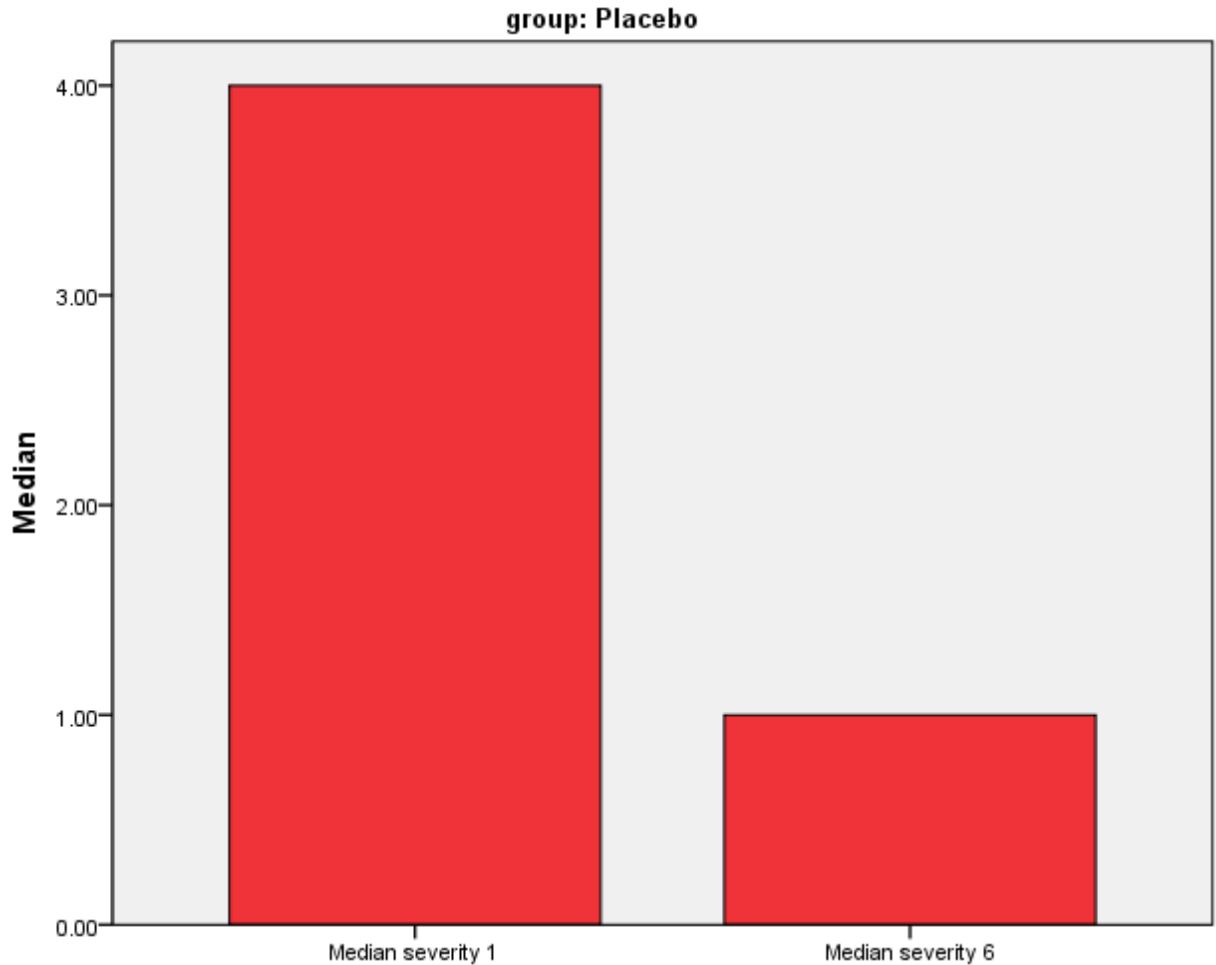


Figure 4.5 : Bar graph of median severity of hot flushes at week 1 and week 6 in the placebo group

Green Climacteric Scale

Scores for all factors were significantly reduced between week 1 (pre treatment) and week 6 (post treatment) in the treatment group. Wilcoxon signed ranks tests showed that mostly participants showed decreases between week 1 and week 6

although some scores increased and some stayed the same. But overall there was significant improvement of symptoms after treatment.

Table 4.7 : Wilcoxon signed ranks tests to compare change in median scores of Green Climacteric scale from week 6 to week 1 within the treatment group (n=31).

		N	Mean Rank	Sum of Ranks
P2 - P1	Negative Ranks	30(a)	16.47	494.00
	Positive Ranks	1(b)	2.00	2.00
	Ties	0(c)		
	Total	31		
A2 - A1	Negative Ranks	30	15.50	465.00
	Positive Ranks	0	.00	.00
	Ties	1		
	Total	31		
D2 -	Negative	29	15.78	457.50

D1	Ranks			
	Positive Ranks	1	7.50	7.50
	Ties	1		
	Total	31		
S2 - S1	Negative Ranks	30	15.50	465.00
	Positive Ranks	0	.00	.00
	Ties	1		
	Total	31		
V2 - V1	Negative Ranks	25	13.00	325.00
	Positive Ranks	0	.00	.00
	Ties	6		
	Total	31		
S2 - S1	Negative Ranks	14	8.21	115.00
	Positive Ranks	1	5.00	5.00
	Ties	16		

	Total	31		
--	-------	----	--	--

a $6 < 1$

b $6 > 1$

c $6 = 1$

group = Treatment group

Table 4.8 : Test Statistics(b,c)

	P2 - P1	A2 - A1	D2 - D1	S2 - S1	V2 - V1	S2 - S1
Z	- 4.827(a)	- 4.792(a)	- 4.632(a)	- 4.795(a)	- 4.399(a)	- 3.216(a)
Asymp. Sig. (2- tailed)	<0.001	<0.001	<0.001	<0.001	<0.001	0.001

a Based on positive ranks.

b Wilcoxon Signed Ranks Test

c group = Treatment group

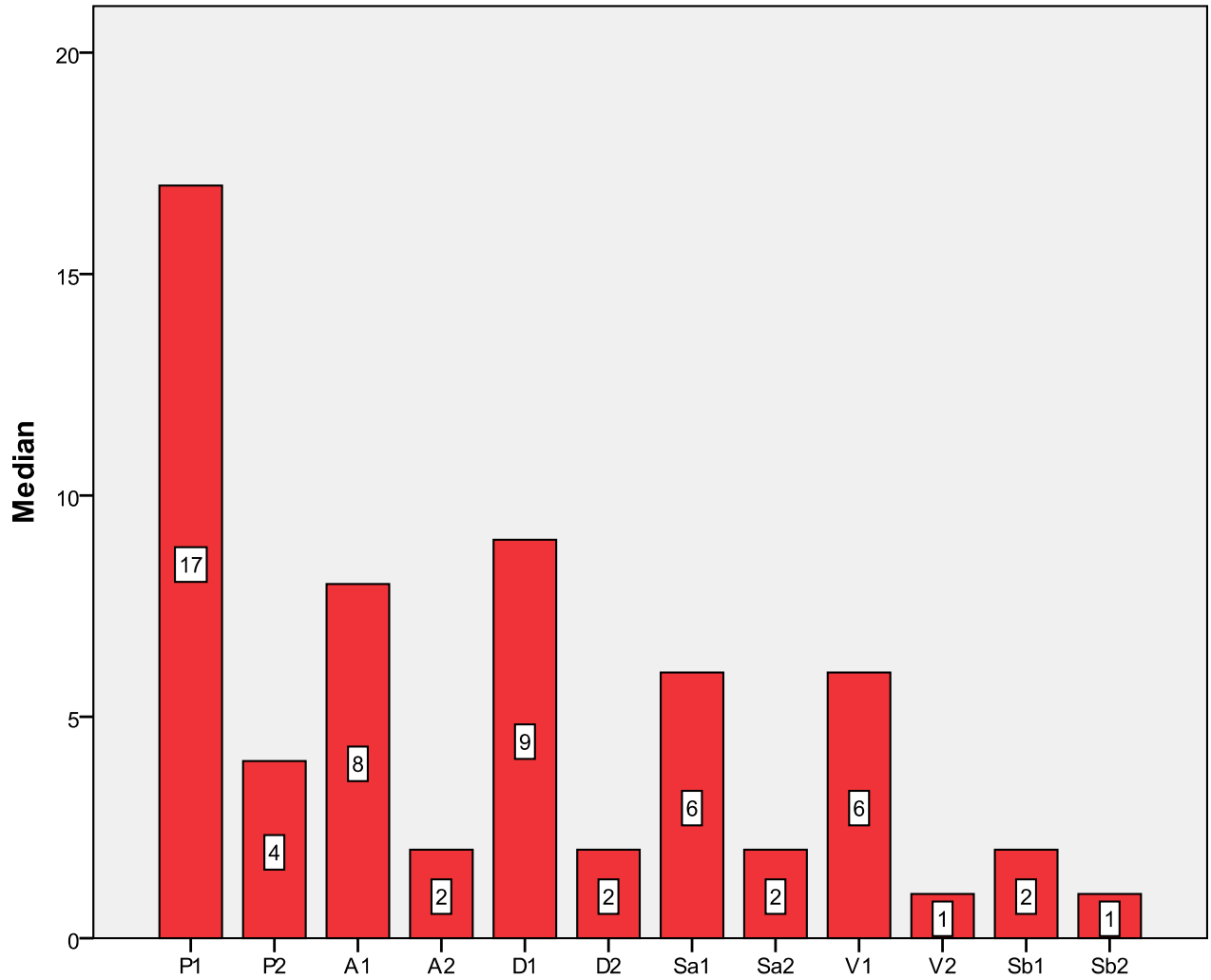


Figure 4.6 : Bar graph of median scores of Green Climacteric scale at week 1 and week 6 in the treatment group

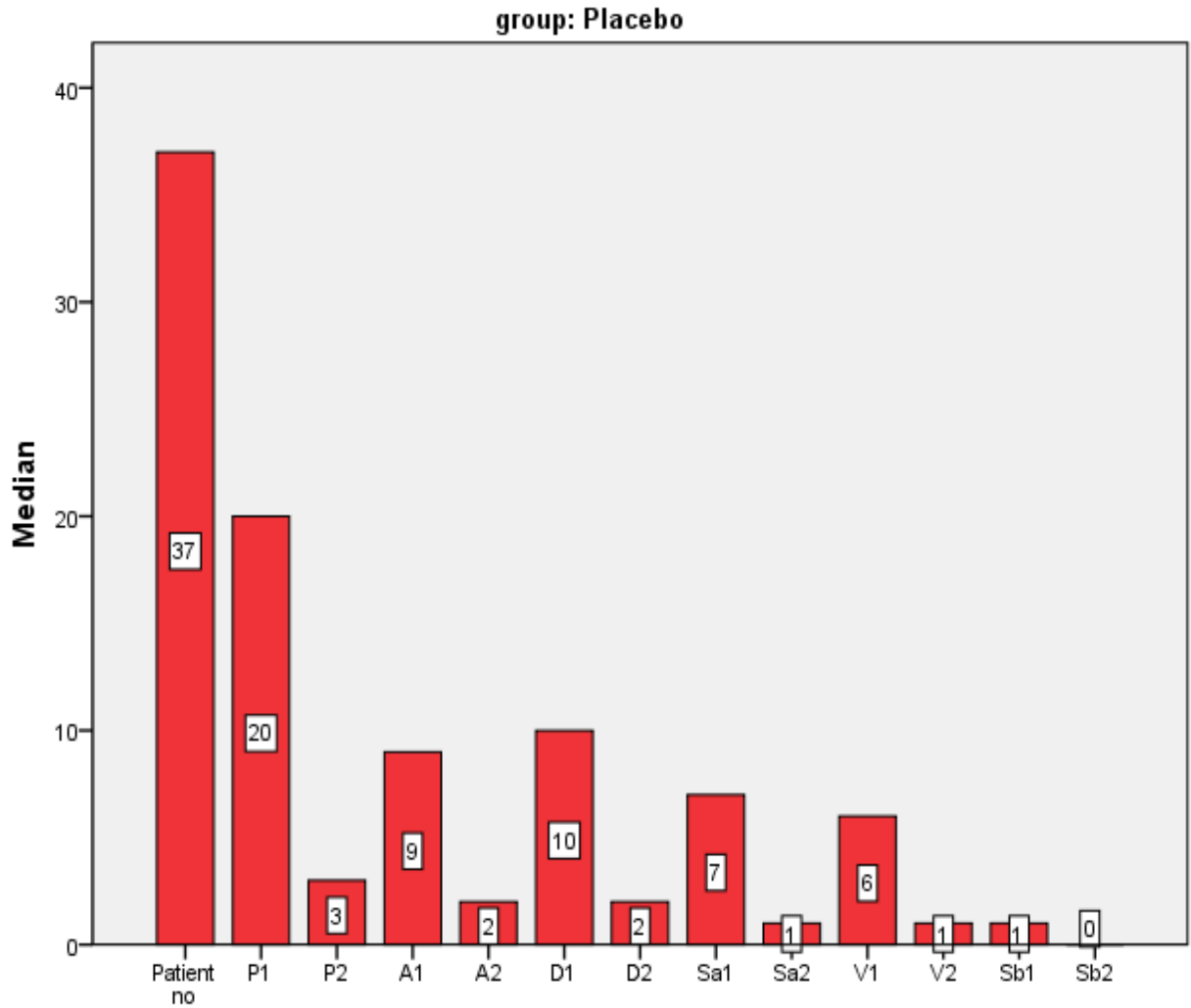


Figure 4.7 : Bar graph of median scores of Green Climacteric scale at week 1 and week 6 in the placebo group

Therefore the first null hypothesis is rejected. We conclude that the complementary formulation of Folliculinum D6 and Five-Flower Formula™

has an effect in the treatment of menopausal symptoms in terms of the participants' perception of treatment.

The second hypothesis

The null hypothesis is that there will be no difference between the results of the complementary formulation and the placebo group in the treatment of menopausal symptoms in terms of the participants' perception of treatment.

Inter-group analysis was done for this hypothesis since the changes between pre and post treatment had to be compared between the treatment and placebo groups in order to establish if the change observed in the treatment group was greater than the change observed in the placebo group.

The Hot Flush Diary

Table 4.9 shows that the number of hot flushes decreased by a median of 4 per day in the treatment group and by a median of 3 per day in the placebo group. The severity of hot flushes decreased by 2 points in the scale on average in both groups.

Table 4.9 : Report of the median changes in number and severity of hot flushes in the treatment and placebo group from pre to post treatment.

Group		Change in number of hot flushes	Change in severity of hot flushes
Treatment group	Median	-4.0000	-2.0000
	Minimum	-20.00	-4.00
	Maximum	10.00	1.00
Placebo	Median	-3.0000	-2.0000
	Minimum	-14.00	-4.00
	Maximum	.00	.00

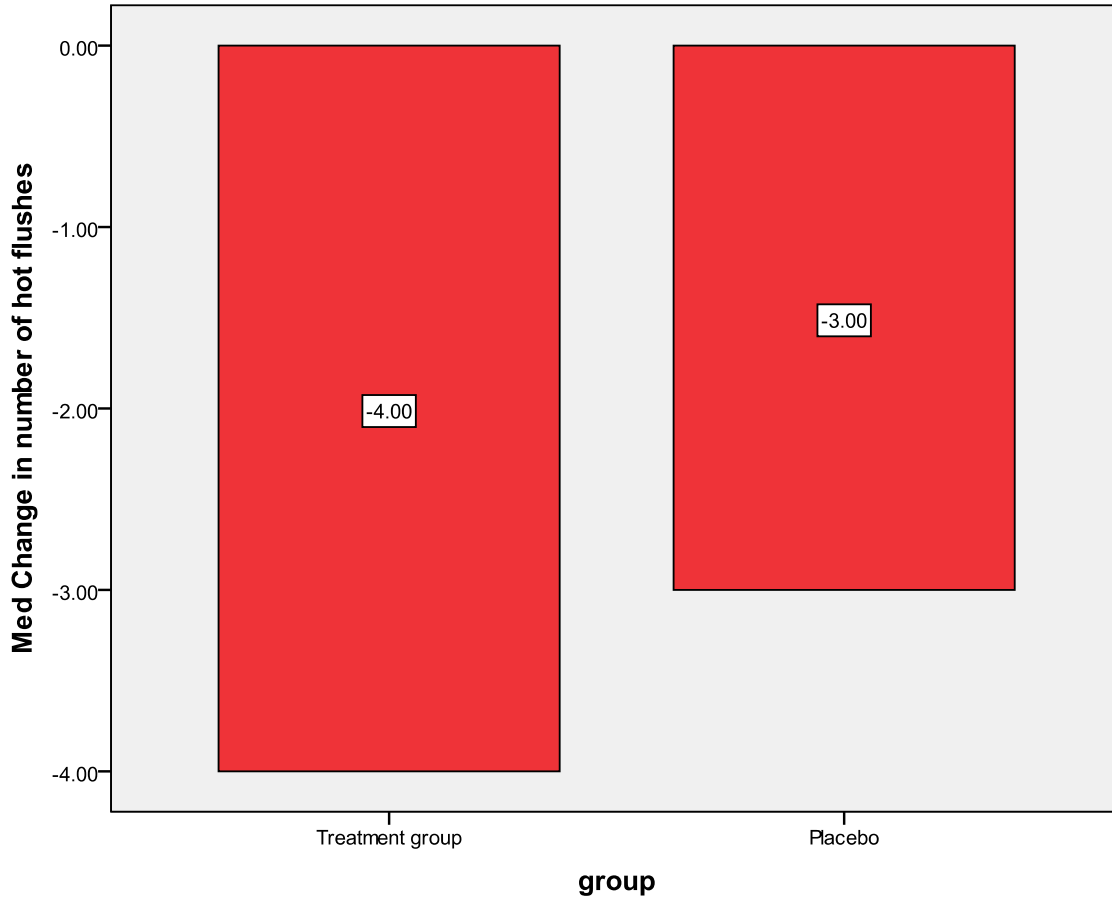


Figure 4.8 : Change in number of hot flushes over time by treatment group or placebo

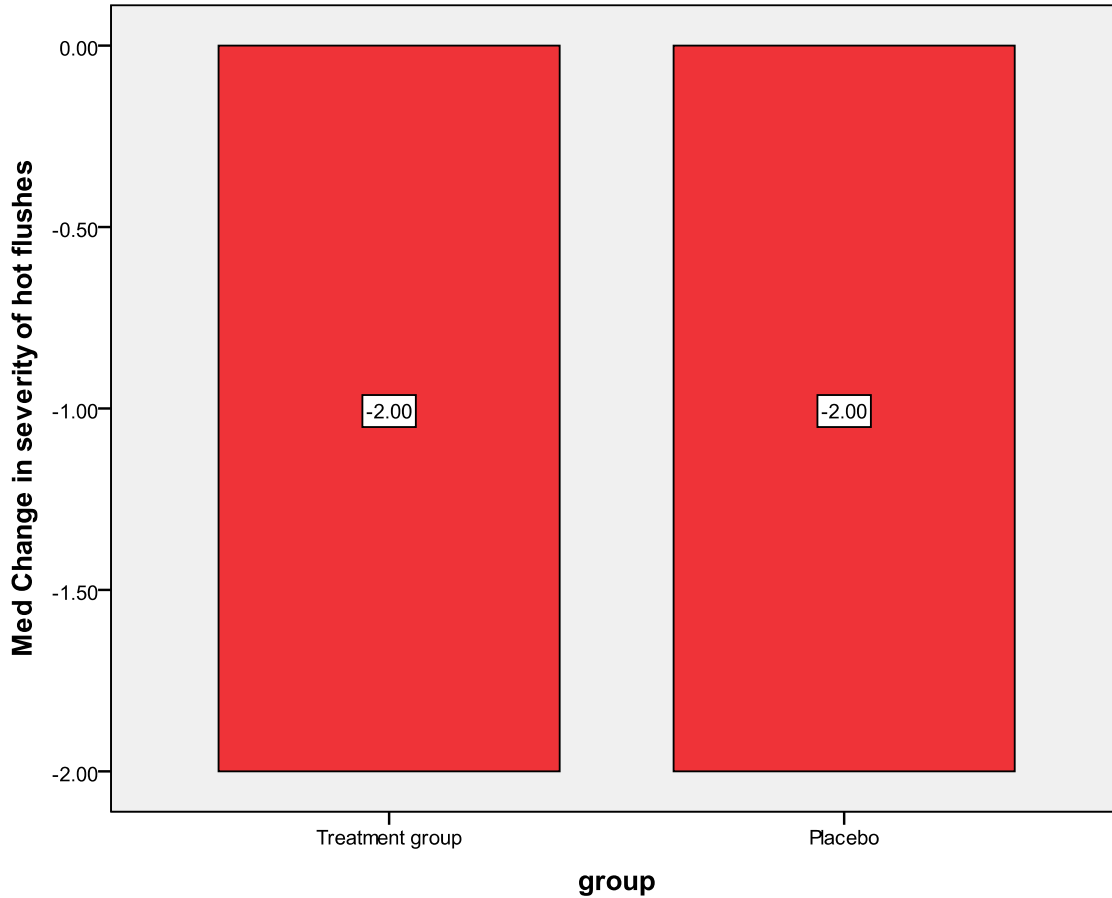


Figure 4.9 : Change in severity of hot flushes over time by treatment group or placebo

Table 4.10 shows that there was no significant difference between the treatment group and the placebo group in terms of the change in either the number or severity of hot flushes ($p=0.337$ and $p=0.125$ respectively).

Table 4.10 : Inter-group comparison of change in number and severity of hot flushes between treatment and placebo groups (n=60)

	group	N	Mean Rank	Sum of Ranks
Change in number of hot flushes	Treatment group	31	28.42	881.00
	Placebo	29	32.72	949.00
	Total	60		
Change in severity of hot flushes	Treatment group	31	33.73	1045.50
	Placebo	29	27.05	784.50
	Total	60		

Table 4.11 : Test Statistics(a)

	Change in number of hot flushes	Change in severity of hot flushes
Mann-Whitney	385.000	349.500

U		
Wilcoxon W	881.000	784.500
Z	-.960	-1.532
Asymp. Sig. (2-tailed)	0.337	0.125

a Grouping Variable: group

Green Climacteric scale

Table 4.12 shows that the scores decreased by slightly more for the first four scales in the treatment group compared to the placebo group but the changes were similar in the two groups for the last two scales.

Table 4.12 : Report of the median changes in scores in the treatment and placebo group from pre to post treatment.

Group		Change in P	Change in A	Change in D	Change in S	Change in V	Change S(b)
Treatment group	Median	- 11.0000	-6.0000	-6.0000	-4.0000	-4.0000	.0000
	Minimum	-26.00	-17.00	-13.00	-15.00	-6.00	-3.00
	Maximum	2.00	.00	3.00	.00	.00	1.00
Placebo	Median	- 14.0000	-8.0000	-6.0000	-5.0000	-4.0000	.0000
	Minimum	-26.00	-14.00	-76.00	-11.00	-6.00	-2.00
	Maximum	-4.00	2.00	-1.00	.00	.00	.00

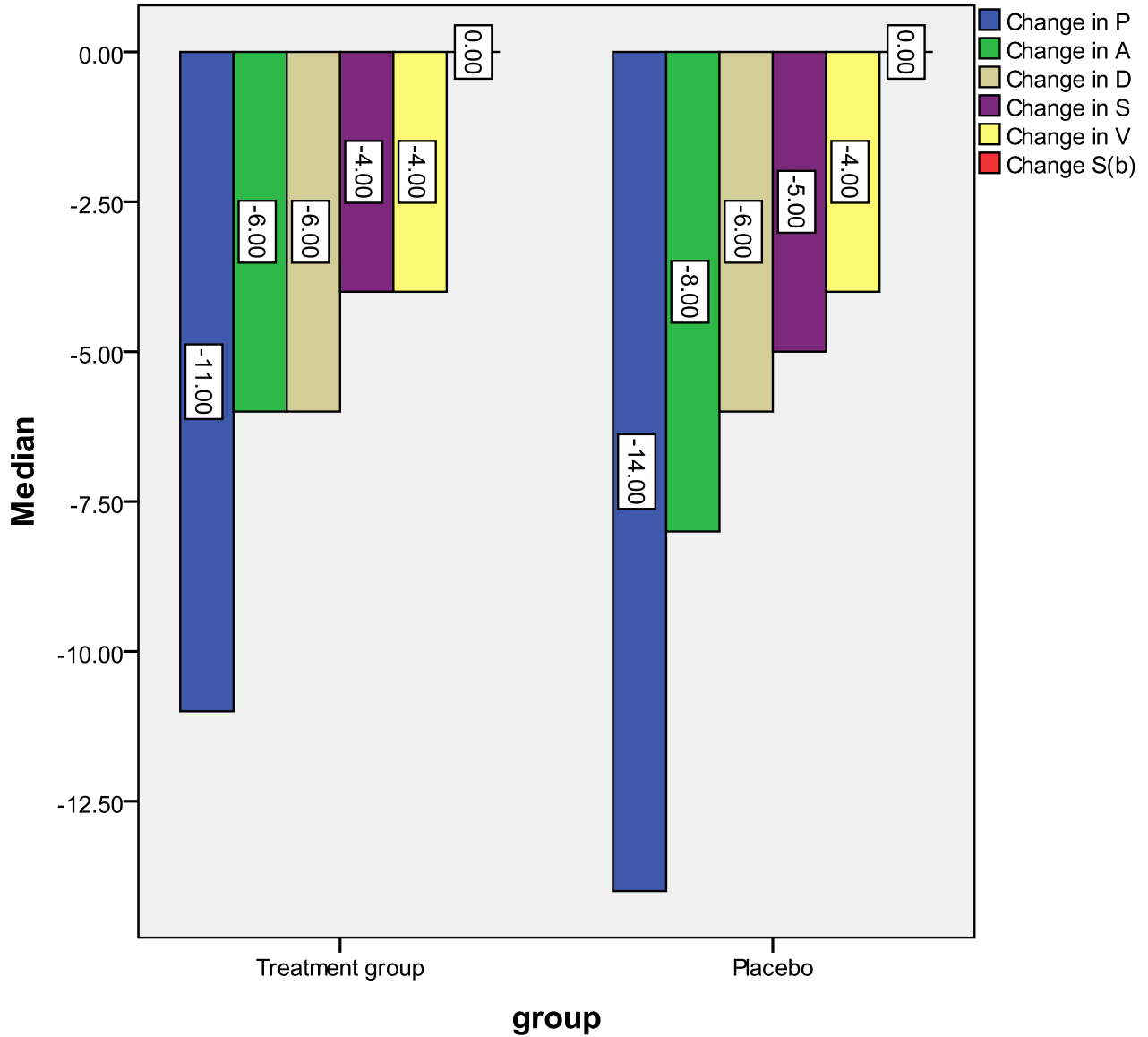


Figure 4.10 : Change in median scores of Green Climacteric scale over time by treatment group or placebo

P represents the psychological scale which is the sum of symptoms 1 to 11.

The P scale is further subdivided to provide measures for anxiety, depression and sexual dysfunction.

A represents anxiety which is the sum of symptoms 1 to 6.

D represents depression which is the sum of symptoms 7 to 11.

S represents the somatic scale which is also the physical scale and consists of symptoms 12 to 18.

V represents the vasomotor scale which is the sum of symptoms 19 to 20.

S (b) represents sexual dysfunction which is symptom 21.

Table 4.13 shows that there were no significant differences between the treatment group and the placebo group in terms of the change in any of the scales. All p values are greater than 0.05.

Table 4.13 : Inter-group comparison of change in scores between treatment and placebo groups (n=60)

	Group	N	Mean Rank	Sum of Ranks
Change in P	Treatment group	31	32.84	1018.00
	Placebo	29	28.00	812.00
	Total	60		
Change in A	Treatment group	31	32.74	1015.00
	Placebo	29	28.10	815.00
	Total	60		

Change in D	Treatment group	31	33.35	1034.00
	Placebo	29	27.45	796.00
	Total	60		
Change in S	Treatment group	31	31.74	984.00
	Placebo	29	29.17	846.00
	Total	60		
Change in V	Treatment group	31	33.71	1045.00
	Placebo	29	27.07	785.00
	Total	60		
Change S(b)	Treatment group	31	30.11	933.50
	Placebo	29	30.91	896.50
	Total	60		

Table 4.14 : Test Statistics(a)

	Change in P	Change in A	Change in D	Change in S	Change in V	Change S(b)

Mann-Whitney U	377.000	380.000	361.000	411.000	350.000	437.500
Wilcoxon W	812.000	815.000	796.000	846.000	785.000	933.500
Z	-1.076	-1.032	-1.314	-.574	-1.495	-.197
Asymp. Sig. (2-tailed)	0.282	0.302	0.189	0.566	0.135	0.844

a Grouping Variable: group

Therefore the second null hypothesis is not rejected. We conclude that while the complementary formulation of Folliculinum D6 and Five-Flower Formula™ seemed to have an effect in the treatment of menopausal symptoms, the effect was no different to that found in the placebo group, and thus the effect cannot be attributed to the treatment.

CHAPTER FIVE: DISCUSSION

AGE

The average age of participants was 50.

HOT FLUSHES

Before treatment, participants were required to fill out a hot flush diary in order to acquire a baseline range of the number and severity of hot flushes experienced.

The results showed that the baseline reading was 10 hot flushes per day (prior to treatment). As can be seen in Figure 4.8, in the treatment group this decreased by a median of 4 per day. In the placebo group this figure decreased by a median of 3 per day. This shows that both groups decreased in the number of hot flushes experienced. Table 4.10 shows these changes in both groups and that there is no statistical difference between the treatment group and the placebo group.

Figure 4.9 demonstrates the severity of the hot flushes in both groups and shows an average decrease of 2 points therefore proving no statistical difference between the groups.

GREEN CLIMACTERIC SCALE

The Wilcoxon signed ranks tests were used to compare the change in median scores of the Green Climacteric Scale in the treatment group. The study showed a drastic improvement in symptoms by week 6 in the treatment group (Table 4.12).

Figure 4.10 shows no significant difference between the 2 groups post treatment, however the treatment group demonstrates a greater decrease in psychological symptoms compared to the placebo group.

Table 4.13 shows no significant statistical difference between both groups regarding change in any of the scales measured.

CONCLUSION

This study was designed to evaluate the effectiveness of a complementary formulation of Folliculinum D6 and Five-Flower Formula™, (Folliculinum D6, Rock Rose, Impatiens, Clematis, Star of Bethlehem, Cherry Plum.) in the treatment of menopausal symptoms in terms of the participants' perception of the treatment.

A significant improvement was demonstrated after treatment in both the treatment group and the placebo group however, the results of this particular study showed that there was no overall significant improvement in the participants experiencing menopausal symptoms who received treatment with

the complementary formulation compared to those participants who received placebo.

In order for a specific treatment to be deemed effective for menopausal complaints it needs to show a significantly better therapeutic effect than placebo.

The only symptoms that improved in the treatment group were the number of hot flushes (Figure 4.8) and the psychological symptoms (Table 4.13). There were no significant differences between the treatment group and placebo group in terms of change in any of the scales as all p values are greater than 0.05. However, it is interesting to note that the number of hot flushes decreased and this symptom is the most common reason for participants to seek treatment during menopause and has the most negative impact on quality of life.

Although the GCS showed an improvement in the psychological symptoms (Figure 4.10), the sub-variables do not show an improvement, thus it cannot be determined exactly which aspect of the psychological symptoms improved. Even though there was a decrease in the number of hot flushes (table 4.9), in the GCS, the vasomotor variable did not show any improvement, therefore even though the number of hot flushes decreased, the intensity and night sweats did not.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

The conclusion reached in this study is that the complementary formulation of *Folliculinum* D6 and Five-Flower Formula™, (*Folliculinum* D6, Rock Rose, Impatiens, Clematis, Star of Bethlehem, Cherry Plum) is ineffective in the treatment of menopausal symptoms in terms of the participants' perception of the treatment.

6.2 DIFFICULTIES ENCOUNTERED

The improvements noted in both groups may be attributed to the natural progression of menopause and not the treatment.

Menopause produces a number of symptoms, some being physical in nature and other psychological. It was challenging in many instances to determine which psychological symptoms were produced by a hormone imbalance and which were due to simultaneous life circumstances such as problematic relationships with spouse or children or work stress.

Another impediment was encountered regarding the GCS was the somatic variable which consisted of symptoms such as joint pain and headaches, both of which could be unrelated to the onset of menopause and merely coincidental.

Due to the nature of the trial, patient compliance was crucial. The researcher had to rely on participants to maintain accurate records of their symptoms as specified by the researcher. The assumption was made that participants took the medication as instructed by the researcher. It is possible that not all the participants followed through with the instructions and this could have affected the results of this study.

Many participants failed to remember their follow up and the second GCS scores were recorded after they had stopped taking the medication.

Participants may have benefitted from a longer treatment period as this would have provided time for the placebo effect to wear off.

6.3 RECOMMENDATIONS

- A larger sample size may be used for further studies in order to obtain greater statistical accuracy.
- The duration of this trial was six weeks. A longer trial period may be used in further studies.

- Future studies may use a different potency, for example Folliculinum 30CH combined with the bach flower remedies.
- Subsequent studies may also prescribe a different dosage, for example 1 tablet every evening.
- Homoeopathic research into the treatment of menopausal symptoms using purely homoeopathic remedies in a complex.
- Homoeopathic studies comparing the similimum with a complementary formulation in the treatment of menopausal symptoms.
- Research comparing the treatment of menopausal symptoms either with a similimum or homoeopathic complex with an alternative complementary treatment such as phytotherapy.
- Since menopause brings on such a multitude of symptoms, it is recommended that the treatment be evaluated together with lifestyle adjustments, such as better eating regimes and exercise.

REFERENCES

Assilem, M. 1991. Folliculinum-Mist or Miasm? Homoeopath. Vol. 11(1), pp. 5-12.

Beers, M., Fletcher, A., Jones, T., Porter, R., Berkwits, M., Kaplan, J. (ed.) 2003. The Merk Manual of Medical Information. 2nd Home ed. Merck Research Laboratories, United States of America. ISBN 0-911910-35-2.

Beers, M., Porter, S., Jones, T., Kaplan, J. and Berkwits, M. (ed.) 2006. The Merk Manual of Diagnosis and Therapy. 18th ed. Merck Research Laboratories, United States of America. ISBN 10:0-911910-18-2.

Berek, J. 2007. Berek & Novak's Gynecology. 14th ed. Lippincott Williams & Wilkins, United States of America. ISBN 13: 978-0-78176-805-4.

Bickley, L., Szilagyi, P. 2003. Bates' Guide to Physical Examination and History Taking. 8th ed. Lippincott Williams & Wilkins, Philadelphia. ISBN 0-7817-3511-4.

Bloch, R., Lewis, B. 2003. Homoeopathy for the Home. Struik Publishers, Cape Town. ISBN 1-86872-843-9.

British Homoeopathic Association. 1991. German Homoeopathic Pharmacopoeia. Deutscher Apotheker-Verlag Stuttgart, Frankfurt. ISBN 3-7692-1386-6.

Chancellor, P. 1995. Illustrated Handbook of the Bach Flower Remedies. C. W. Daniel Company Ltd, England. ISBN 0-85207-002-0

Chatta, R., Kulkarni, R., Nagarathna, R., Nagendra, H.R. 2008. Factor analysis of Greene's Climacteric Scale for Indian Women. Maturitas. Vol. 59, pp. 22-27.

Chevallier, A. 2007. Herbal Remedies. Dorling Kindersley Limited, London. ISBN 978-1-4053-1282-0.

Domleo, S. 2002. The Homoeopathic Treatment of Menopausal Symptoms With Folliculinum 30CH. Dissertation, M. dip. Hom. Technikon Natal, Durban.

Glenville, M. 1998. Natural Alternatives to HRT. Greenwich Editions, London. ISBN 0-86288-128-5.

Guyton, A., Hall, J. 2005. Textbook of Medical Physiology. 11th ed. W.B. Saunders Company, United States of America. ISBN 0-7216-02401.

Hacker, N., Moore, J., Gambone, J. 2004. Essentials of Obstetrics and Gynecology. 4th ed. Elsevier Saunders, China. ISBN 0-7216-0179-0.

Hagen, S. 1995. Menopausal Syndrome. Dissertation, M. Dip. Hom. Technikon Natal, Durban.

Heinemann, L., DoMinh, T., Strelow, F., Gerbsch, S., Schnitker, J., Schneider, H. 2003. International Versions of the Menopause Rating Scale (MRS). Health and Quality of Life Outcomes (online), 1:28.

Available WWW: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC183844/>

(Accessed 4 November 2008).

Howard, J. 2005. Bach Flower Remedies for Women. Vermilion, London. ISBN 009190654-7.

Julian, O. 1979. Materia Medica of New Homoeopathic Remedies. University Press, Oxford. ISBN 0-906584-11-6. pp.231-235.

Kayne, S. 1997. Homoeopathic Pharmacy, an introduction and handbook. Longman Singapore Publishers (Pte) Ltd, Singapore. ISBN 0-443-05018-X.

Kirtland, K. 1994. The Efficacy of Folliculinum in the Treatment of Premenstrual Tension. Dissertation, M. Dip. Hom. Technikon Natal, Durban.

Lockie, A. 2006. Encyclopedia of Homeopathy. Dorling Kindersley Ltd, New York.

Macquet-Maurel, L. 2003. The Efficacy of Dioscorea Villosa Cream in the Treatment of Menopausal Syndrome. Dissertation, M. Dip. Hom. Technikon Natal, Durban.

McTeer, T. 2003. The Efficacy of ProgestoNat Cream in the Treatment of Menopausal Syndrome. Dissertation, M. Dip. Hom. Technikon Natal, Durban.

Mattox, J. 1998. Core Textbook Of Obstetrics & Gynecology. Mosby, United States of America. ISBN 0-8151-6035-6.

Mills, S., Bone, K. 2007. Principles and Practice of Phytotherapy Modern Herbal Medicine. Churchill Livingstone, London. ISBN 0-443-06016-9.

Natura Laboratory. 2003. Procedure for medicating of tablets, SOP NO: DL6-5. Pretoria, South Africa.

Nazario, B. 2003. Dangers of Black Cohosh as HRT.

(<http://www.medscape.com/viewarticle/530107> - (accessed 12 November 2008))

Northrup, C. 2009. The Wisdom of Menopause. Piatkus Books, London. ISBN 978-0-7499-2737-0.

Oats, J., Abraham, S. 2005. Fundamentals of Obstetrics and Gynaecology. 8th ed. Elsevier MOSBY, Spain. ISBN 0723433305.

Scheffer, M. 1990. Bach Flower Therapy Theory and Practice. Thorsons, London. ISBN 0-7225-1121-3.

Sloan, J., Loprinzi, C., Novotny, P., Barton, B., Lavasseur, B., Windschitl, H. 2001. Methodologic Lessons Learned From Hot Flash Studies. Journal of Clinical Oncology. Vol. 19, Issue 23, pp. 4280-4290.

Stanfield, C., Germann, W., 2008. Principles of Human Physiology. 3rd ed. Pearson Benjamin Cummings, United States of America. ISBN 0-321-45428-6.

Stengler, A., Stengler, M. 2003. Your Menopause, Your Menotype. Prentice Hall Press, New York. ISBN 1-58333-158-1.

Stoppler, M. 2010. Menopause (Perimenopause).

<http://www.medicinenet.com/script/main/art.asp?articlekey=2036> – (accessed 10 January 2011)

Sturdee, D. 2003. The Facts of Hormone Therapy for Menopausal Women. The Parthenon Publishing Group Limited, London. ISBN 1-85070-807-X.

Symonds, E., Symonds, I. 2004. Essential Obstetrics and Gynaecology. 4th Ed. Churchill Livingstone, Spain.

Wang-Cheng, R. 2007. Menopause. American College of Physicians, United States of America. ISBN 978-1-930513-83-9.

LIST OF APPENDICES

- Appendix A: Advertisement
- Appendix B: Letter of Permission
- Appendix C: Participant Information Letter
- Appendix D: Informed Consent
- Appendix E: Case History
- Appendix F: Manufacturing of Tablets
- Appendix G: Guidelines on Taking Medication
- Appendix H: Menopause Rating Scale
- Appendix I: Green Climacteric Scale
- Appendix J: Hot Flush Diary

APPENDIX A

FREE HOMOEOPATHIC TREATMENT

FOR MENOPAUSE SYMPTOMS

DO YOU SUFFER FROM :

- HOT FLUSHES
- MOOD SWINGS
- NIGHT SWEATS
- DECLINING LIBIDO
- WEIGHT GAIN
- LACK OF ENERGY

YOU MAY QUALIFY FOR FREE TREATMENT at the

Durban University of Technology

If you are willing to participate in this Masters Degree research project and you fulfil the selection criteria

The study will INCLUDE those that fulfil the following criteria:

- Perimenopausal women, menopausal women or women experiencing menopausal symptoms.
- Perimenopausal women
- Women experiencing natural menopause
- Women who have undergone a partial hysterectomy (ovaries remaining)

- Women NOT on any other forms of naturopathic/homoeopathic/allopathic treatment for menopausal symptoms 3 weeks before their commencement in the trial

Those participants with the following will be EXCLUDED from this study

- Women who have undergone a complete hysterectomy (ovaries removed)
- Women on current hormonal therapy

For further information or to book your appointment, call

FATIMA HANSA on 072 3707 333

APPENDIX B

Date : _____

To : Dr Naude

Clinic Director

Homoeopathic Day Clinic

Durban University of Technology

USE OF CLINIC FACILITIES

I, Fatima Hansa (4th year Homoeopathic student) kindly request permission to use the Homoeopathic Day Clinic for research purposes in 2009.

My research topic is “To investigate the efficacy of a complementary formulation of Folliculinum D6 and Five-Flower Formula™, (Folliculinum D6, Rock Rose, Impatiens, Clematis, Star of Bethlehem, Cherry Plum) in the treatment of menopausal symptoms”.

This study will last for 7 weeks. There will be 2 consultations that will be 7 weeks apart. The initial consultation will be 1 hour long and each follow-up consultation will be 30 minutes in duration. The clinic facilities that will be utilised are the reception area, dispensary and consultation room.

60 participants will be selected for the study and recruited on the basis of inclusion and exclusion criteria :

Inclusion criteria :

- Perimenopausal women, menopausal women or women experiencing menopausal symptoms.
- Women experiencing natural menopause
- Women who have undergone a partial hysterectomy (ovaries remaining)
- Women NOT on any other forms of naturopathic/homoeopathic/allopathic treatment for menopausal symptoms 3 weeks before their commencement in the trial

Exclusion criteria :

- Women who have undergone a complete hysterectomy (ovaries removed)
- Women on current hormonal therapy

I await your favourable response as soon as possible.

Thank you

Yours truly,

Fatima Hansa , student number : 20204521
M.Tech Homoeopathy , Tel: 072 3707 333

APPENDIX C

Dear Participant.

Thank you for your time and interest taken in this research project. With your assistance the efficacy of a complementary formulation can be investigated in the treatment of menopausal symptoms.

I am a Masters degree student at Durban University of Technology. In order to qualify as a homoeopath I am required to complete a dissertation. This study aims at investigating the efficacy of a complementary formulation, in the treatment of menopausal symptoms. Many women experience unpleasant symptoms such as hot flushes, mood swings, irritability and loss of libido which can severely compromise their quality of life.

Hormone replacement therapy (HRT) is the most common treatment for these symptoms, but has many unpleasant side effects. Homoeopathy offers a safe and effective treatment of menopausal symptoms.

Sixty people will be required to complete this study. In order to ensure that this research complies with the scientific method only certain people will be accepted as part of the research.

Inclusion criteria :

- Perimenopausal women, menopausal women or women experiencing menopausal symptoms.
- Women experiencing natural menopause.
- Women who have undergone a partial hysterectomy (ovaries remaining).
- Women NOT on any other forms of naturopathic/homoeopathic/allopathic treatment for menopausal symptoms 3 weeks before their commencement in the trial.

Exclusion criteria

- Women who have undergone a complete hysterectomy (ovaries removed)
- Women on current hormonal therapy

This study is a double blind placebo-controlled study. The participants will be randomly divided, by means of a randomisation sheet drawn up by the supervisor, between treatment and placebo groups. The placebo group will receive tablets that are unmedicated. The treatment groups will be given tablets that contain the following ingredients :

- Folliculinum D6
- Rock Rose D6
- Impatiens D6
- Clematis D6
- Star of Bethlehem D6
- Cherry Plum D6

Benefits of the study

The benefit of this study is that the participants in the treatment groups will be given free treatment for their symptoms of menopausal syndrome. The placebo group will be given free treatment at the end of the study. Participants will also have the opportunity to gain more knowledge of menopause.

Remuneration

No remuneration will be offered to any of the participants in this study.

Procedure of the study

At the first consultation you will have a complete case history taken and a physical examination will be performed.

Participation in this study requires that you take the medication (which will be either the homoeopathic complex or placebo) as instructed by the researcher and that you are not on HRT, any other treatment for menopausal symptoms or any medication that may affect your symptoms.

You will be required to consult with the researcher and complete the relevant questionnaires. You will be given a Hot Flush Record chart to fill in daily one week prior to taking the medication and the last(6th) week of the study and this will be handed to the researcher at the end of the study.

Your commitment to the study in terms of taking the medication as prescribed, completing the' questionnaires as honestly as possible and attending consultations with the researcher at appointed times will be greatly appreciated and you will be providing valuable information to be used in evaluating the effectiveness of this complex as an alternative treatment for menopausal symptoms.

All information provided in the questionnaires will be regarded as **strictly confidential** and will only be viewed by the researcher and supervisor.

Risks and Discomfort

Complications are not expected from the above treatment nor the placebo group. Participants do have the option of withdrawing from the study without motivation

The treatment is supervised by a qualified homoeopath and is free of charge. In case of any queries or problems that may arise during the study please contact :

Fatima Hansa tel : 072 3707 333

Supervisor : Dr Ingrid Couchman, M.Tech.Hom(TN)-(031-373 2041)

Kind Regards

Fatima Hansa

(6th year homoeopathy students)

Department of Homoeopathy , Durban University of Technology

Patient Name: _____

Signature : _____

Witness Name : _____

Signature : _____

APPENDIX D

INFORMED CONSENT FORM

(To be completed in duplicate by the patient)

TITLE OF RESEARCH PROJECT:

To investigate the efficacy of a complementary formulation of Folliculinum D6 and Five-Flower Formula™, in the treatment of menopausal symptoms.

NAME OF SUPERVISOR:

Dr Ingrid Couchman (M.Tech :Hom)

NAME OF RESEARCH STUDENT:

Fatima Hansa (6th year Homoeopathy student)

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? | YES/NO |
| 5. Have you received enough information about this study? | YES/NO |
| 6. Who have you spoken to? _____ | |
| 7. Do you understand the implications of your involvement in the study? | YES/NO |
| 8. 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 the study? | YES/NO |
| 11. Do you understand the difference between a placebo and homeopathic treatment? | YES/NO |
| 12. If you have answered “NO” to any of the above questions please obtain the information before signing. | |

PATIENT NAME: _____ SIGNATURE: _____

WITNESS NAME: _____ SIGNATURE: _____

RESEARCH STUDENT: _____ SIGNATURE: _____

APPENDIX E

CASE HISTORY QUESTIONNAIRE

(Bickley, Szilagyi, 2003)

DATE: _____

PATIENT NO.: _____

SURNAME: _____

FIRST NAMES: _____

AGE: _____

SEX: _____

OCCUPATION: _____

MARITAL STATUS: _____

CHILDREN _____

ADDRESS:

TELEPHONE _____

MAIN COMPLAINT : WHAT SEEMS TO BE THE PROBLEM ?

HISTORY OF MAIN COMPLAINT:

(ONSET, LOCATION, AETIOLOGY, DURATION, CHARACTER MODALITIES,
CONCOMITANTS, RADIATION, PARTICIPANTS RESPONSE TO SYMPTOMS)

PAST MEDICAL HISTORY:

(RHEUMATIC FEVER, PNEUMONIA, TUBERCULOSIS, JAUNDICE, HIGH
BLOOD PRESSURE)

PAST SURGICAL HISTORY:

DID YOU HAVE ANY OPERATION SINCE YOU WERE BORN?

CHILDHOOD DISEASES/ILLNESSES:

(MUMPS, MEASLES, CHICKEN POX, GERMAN MEASLES, TUBERCULOSIS)

TONSILS:

ALLERGIES:

VACCINATION HISTORY:

FAMILY HISTORY:

(TB, DIABETES, HEART DISEASE, HYPERTENSION, STROKE, ASTHMA,
ARTHRITIS, ANAEMIA, HEADACHES, EPILEPSY, ECZEMA, KIDNEY
DISEASE, HAYFEVER, CANCER, MENTAL ILLNESSES)

MOTHER :

FATHER :

SIBLINGS :

GRANDPARENTS (MOTHER AND FATHER) :

SOCIAL HISTORY :

1. WHAT ARE YOUR HOBBIES, LEISURE ACTIVITIES AND EXERCISE?

2. DO YOU SMOKE? HOW MANY?

3. DO YOU DRINK ALCOHOL? HOW MUCH? HOW OFTEN?

GENERALS:

ENERGY LEVELS

SLEEP

APPETITE

PERSPIRATION

SEXUAL LIBIDO

MENSES

STDs

SUPPLEMENTS AND OTHER MEDICATIONS

SYSTEMS REVIEW :

HEAD:

HEADACHES

- Types?

- Location?

- Frequency?

- What makes it better/worse?

- Associating symptoms?

EYES:

(Vision, glasses, contact lenses, pain, redness, double vision, cataracts)

EARS:

(Hearing problems, vertigo, tinnitus, earaches, infections, discharge)

NOSE AND SINUSES:

(pain, congestion, nosebleed, frequency of colds, hayfever, loss of smell)

MOUTH AND THROAT:

(Frequency of sore throat, bleeding gums, sore tongue, breath odour, loss of taste)

NECK:

(Swollen glands, pain or stiffness in the neck)

RESPIRATORY SYSTEM:

(Chest pain or discomfort, hypertension, rheumatic fever, murmurs)

GASTROINTESTINAL SYSTEM:

(Heartburn, anorexia, nausea, vomiting, abdominal pains, haemorrhoids, constipation and diarrhoea)

URINARY SYSTEM:

(Infection, burning and pain on urination)

GENITAL SYSTEM:

Female

- menses
- discharge/leucorrhoea

Male

- impotence
- sexual interest

MUSCULOSKELETAL SYSTEM:

(Joint pain, stiffness, arthritis, gout, backache)

NEUROLOGICAL SYSTEM:

(Numbness, paralysis, weakness, faintness)

ENDOCRINE SYSTEM:

(Thyroid trouble, diabetes)

ON EXAMINATION :

VITAL SIGNS:

PULSE

BLOOD PRESSURE

RESPIRATORY RATE

TEMPERATURE

WEIGHT AND HEIGHT

GENERAL OBSERVATIONS:

(State of health, signs of distress, skin colour and possible lesions, sexual development, posture, motor activity and gait, dress, grooming and hygiene, odours of the body and breath. Facial expression, note of awareness and level of consciousness, listen to patient's speech)

GENERAL OBSERVATION :

HEAD: inspection and palpation

Note any - deformities

-lumps

- tenderness, other lesions

FACE: inspection and palpation

Note facial expression and contours, symmetry, involuntary movements, oedema, masses and facial pain.

EYES: inspection and palpation

Note position and alignment. Note pupil size, shape, equality.

Note any redness, swelling, vascular pattern, nodules.

NOSE AND PARANASAL SINUSES : Inspection and palpation

External surface-asymmetry, deformity, inflammation.

Internal surface-Nasal mucosa-colour, swelling, exudates, bleeding. Nasal septum-bleeding, crusting, perforation or deviation Inferior, medial turbinate and middle meatus-colour, swelling, exudates and Polyps.

Palpate the sinuses-frontal sinus tenderness Maxillary sinus tenderness

Postnasal drip-colour, odour, quantity, frequency.

MOUTH AND PHARYNX :

Lips-colour, moisture, swelling. Mouth-breath, taste, pain, lesions.

Teeth-carries, pain, abnormalities in shape, colour and position. Pharynx-tonsils, swellings, lesions, colour, ulceration, uvula.

EARS

Ear drum and canal-discharge and foreign bodies, redness and swelling, cerum, colour and contour.

-handle of malleus

-cone of light

-perforations

NECK

Stiffness and pain

Thyroid gland

Tracheal deviation

JVP

Lymph nodes

THORAX- inspection, palpation and auscultation

- chest wall movement and shape

- auscultation of heart and lungs

ABDOMEN - inspection, palpation and auscultation

- pain, tenderness, guarding spleen, liver, kidneys.

BACK - inspection and auscultation

- symmetry of body

- curvature and orientation of spine

- posture, any restricted movements.

UPPER AND LOWER LIMBS

-hair distribution, colour, temperature, any lesion, any pain and muscle conditions.

AXILLAE- inspection and palpation

4 areas - central - deep

-distal

- pectoral/anterior

-subscapular/posterior

also – supraclavicular

- infraclavicular

APPENDIX F

Manufacturing process of tablets

The tablets are manufactured by the Natura Laboratory in Pretoria and are medicated according to a laid down procedure as per German homoeopathic pharmacopoeia method 9. It is a combination of *Folliculinum* D6 which is added to the 5 flower essences that make up the complex known as Rescue Remedy from Bach. The final medicine is made as a 1000 tablet batch.

The *Folliculinum* is potentised up in 96% ethanol and the Five Flower Essence is in 43 %. That means that the final medicating liquid will be in 90.7% ethanol with which the lactose-based tablets are medicated.

The Five Flower Essences are imported from the UK directly in its mixed form and is added directly to the *Folliculinum* D6. It is a generic prepared by the company Healing Herbs and is made according to the original directions of Dr. Edward Bach (Hohl, 2009).

The containers that are used are of inert material that will not react with the homoeopathic substance such as glass, stainless steel, plastic or paper.

The medicating solution contains 9 parts *Folliculinum* D6 and 1 part Five Flower Essence (Hohl, 2009)

The calculation for the quantity of medicating solution required is as follows :

90 tablets = .68 ml (approximately 16 drops) of appropriate medicated stock.

135 tablets = 1.0 ml (approximately 20 drops) of appropriate medicated stock.

275 tablets = 2.1 ml (approximately 40-42 drops) of appropriate medicated stock.

600 tablets = 4.5 ml (approximately 90 drops) of appropriate medicated stock.

1000 tablets = 7.5 ml (approximately 150 drops) of appropriate medicated stock.

The medicating solution is then added drop wise by hand, distributing evenly over the tablets with constant agitation until the tablets are completely covered in a film of medication solution. The tablets are then allowed to stand until dry making them indistinguishable from the placebo tablets (Natura Laboratory, 2003).

The medicating stock bottle is then used to medicate the unmedicated tablets in a 3% volume to mass ratio with a single impregnation. The final medicine is made as a 1000 Tablet size (Hohl, 2009).

APPENDIX G

GUIDELINES ON TAKING MEDICATION

1. Medication should be taken 30 minutes away from meals.
2. Dosage= 1 tablet on waking in the morning and 1 at night before sleeping.
3. Tablets are to be swallowed with water. Make sure hands are clean when handling tablets.
4. Please store medication in a cupboard away from strong light, heat, perfume or coffee.
5. Please avoid using camphor or drinking coffee while taking homoeopathic medication as these may antidote the remedy.

APPENDIX H

Menopause Rating Scale (MRS)

Which of the following symptoms apply to you at this time? Please, mark the appropriate box for each symptom. For symptoms that do not apply, please mark 'none'.

Symptoms:

	none	mild	moderate	severe	very severe
	-----	-----	-----	-----	
Score	= 0	1	2	3	4

- | | | | | | | |
|-----|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 1. | Hot flushes, sweating
(episodes of sweating)..... | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. | Heart discomfort (unusual awareness of heart
beat, heart skipping, heart racing, tightness)..... | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. | Sleep problems (difficulty in falling asleep,
difficulty in sleeping through, waking up early)..... | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. | Depressive mood (feeling down, sad, on the
verge of tears, lack of drive, mood swings)..... | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. | Irritability (feeling nervous, inner tension,
feeling aggressive)..... | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. | Anxiety (inner restlessness, feeling panicky)..... | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. | Physical and mental exhaustion (general decrease
in performance, impaired memory, decrease in
concentration, forgetfulness)..... | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. | Sexual problems (change in sexual desire, in
sexual activity and satisfaction)..... | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. | Bladder problems (difficulty in urinating,
increased need to urinate, bladder incontinence)..... | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. | Dryness of vagina (sensation of dryness or burning
in the vagina, difficulty with sexual intercourse)..... | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. | Joint and muscular discomfort (pain in the joints,
rheumatoid complaints)..... | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

APPENDIX I

**THE GREENE
CLIMACTERIC SCALE**

NAME: DATE:

NUMBER:

Please indicate the extent to which you are bothered at the moment by any of these symptoms by placing a tick in the appropriate box.

SYMPTOMS	Not at all	A little	Quite a bit	Extremely	Score 0-3
1. Heart beating quickly or strongly					
2. Feeling tense or nervous					
3. Difficulty in sleeping					
4. Excitable					
5. Attacks of panic					
6. Difficulty in concentrating					
7. Feeling tired or lacking in energy					
8. Loss of interest in most things					
9. Feeling unhappy or depressed					
10. Crying spells					
11. Irritability					
12. Feeling dizzy or faint					
13. Pressure or tightness in head or body					
14. Parts of body feel numb or tingling					
15. Headaches					
16. Muscle and joint pains					
17. Loss of feeling in hands or feet					
18. Breathing difficulties					
19. Hot flushes					
20. Sweating at night					
21. Loss of interest in sex					

P (1-11) =
 S (12-18) =
 V (19-20) =

A (1-6) =
 D (7-11) =
 S (21) =

APPENDIX J

HOT FLUSH DIARY

WEEK 1 (BASELINE) : NO TABLETS THIS WEEK

Date week started: / /
 m m d d y y y y

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7**
Number of today's hot flashes that were mild, moderate, severe, or very severe?	<u> </u> mild <u> </u> moderate <u> </u> severe <u> </u> very severe	<u> </u> mild <u> </u> moderate <u> </u> severe <u> </u> very severe	<u> </u> mild <u> </u> moderate <u> </u> severe <u> </u> very severe	<u> </u> mild <u> </u> moderate <u> </u> severe <u> </u> very severe	<u> </u> mild <u> </u> moderate <u> </u> severe <u> </u> very severe	<u> </u> mild <u> </u> moderate <u> </u> severe <u> </u> very severe	<u> </u> mild <u> </u> moderate <u> </u> severe <u> </u> very severe
Total number of hot flashes today*							

* One day should be considered to be a 24 hour period (i.e. 7:00 a.m. to 7:00 a.m. or midnight to midnight).

Date week stopped: / /
 m m d d y y y y

WEEK 6 (IFNAL WEEK OF TREATMENT)

Date week started: / /
 m m d d y y y y

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7**
Number of today's hot flashes that were mild, moderate, severe, or very severe?	<u> </u> mild <u> </u> moderate <u> </u> severe <u> </u> very severe	<u> </u> mild <u> </u> moderate <u> </u> severe <u> </u> very severe	<u> </u> mild <u> </u> moderate <u> </u> severe <u> </u> very severe	<u> </u> mild <u> </u> moderate <u> </u> severe <u> </u> very severe	<u> </u> mild <u> </u> moderate <u> </u> severe <u> </u> very severe	<u> </u> mild <u> </u> moderate <u> </u> severe <u> </u> very severe	<u> </u> mild <u> </u> moderate <u> </u> severe <u> </u> very severe
Total number of hot flashes today*							

* One day should be considered to be a 24 hour period (i.e. 7:00 a.m. to 7:00 a.m. or midnight to midnight).

Date week stopped: / /
 m m d d y y y y