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How to cite this thesis
THE EFFICACY OF THE HOMOEOPATHIC COMPLEXES Dr RECKEWEG R10®
AND R20® IN THE TREATMENT OF SYMPTOMS OF THE CLIMACTERIC

A dissertation submitted to the Faculty of Health Sciences, University of Johannesburg, as
partial fulfillment for the Masters degree in Homoeopathy by

Sainani Charles Muila
(Student number: 802013187)

UNIVERSITY
OF
JOHANNESBURG

Supervisor:  

Co-Supervisor:  

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To Statkon, for assisting with my statistics.

To the GOD of Mount Zion, You delivered me.
DEDICATION

This study is dedicated to my mother (Maboko), my siblings (Murivhula, Modjadji, Mphabantshi, Muraga, Mutheiwa) and my wife who were behind me studying Homoeopathy.
ABSTRACT

The climacteric describes the ongoing changes and symptoms, of the phase or transition period that may last 15-20 years in a woman's lifecycle, when ovarian function and hormonal production declines. Menopause is the permanent cessation of the menses, identified retrospectively after one year without menses and occurs within this period of climacteric (Bernstein et al. 1996). The most common symptoms of climacteric include hot flushes, night sweats, sleep disturbances, nervousness, depressive moods, feelings of vertigo, inability to concentration, joint pain, headache and heart palpitations. The most commonly used allopathic medication to palliate these symptoms is hormone replacement therapy (HRT). There are adverse side effects and risks associated with this treatment and not all women feel better on HRT (Stoppard, 2001).

The aim of this research study was to determine the efficacy of the Homoeopathic complexes Dr Reckeweg R10® and R20® (Homoeopathic complexes) in relieving the symptoms of the climacteric.

The methodology and Ethics were accepted by Higher Degrees Committee and Academic Ethics Committee on the 25 August 2008 (Ethical clearance no: 40/08).

Participants were recruited by advertisements (Appendix A) at the University of Johannesburg, in health food shops and in pharmacies. This was a double blind, placebo controlled study involving thirty-two participants who were divided into two matched groups based on the severity of the menopausal symptoms. Volunteers were selected using the exclusion and inclusion criteria. Volunteers meeting the inclusion criteria completed the information and consent form (Appendix B), and a patient profile and case history (Appendix C) were taken. The participants were randomly allocated to an experimental or control group, and given sets of medication (Remedy A and B, 50ml bottles) to take for a period of eight weeks (Appendix D). The participants took 10 drops of Remedy A (R10® or placebo) in the morning and Remedy B (R20® or placebo) at night. The participants were requested to complete the abbreviated Kupperman Menopause Index (KMI) weekly. The abbreviated KMI (Appendix E) scores were added
up on the participant’s full KMI (Appendix F) at the end of the trial (Kupperman et al. 1959).

The results of this study showed that treatment with the Homoeopathic complexes Dr Reckeweg R10® and R20® was significantly effective in alleviating the climacteric symptoms.
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CHAPTER ONE

INTRODUCTION

1.1 PROBLEM STATEMENT

The climacteric describes the ongoing changes and symptoms of the phase or transition period that may last 15-20 years in a woman's lifecycle, when ovarian function and hormonal production declines. It can also be defined as the syndrome of endocrine, somatic and psychological changes occurring at the termination of the reproductive period in the female (Luciano et al. 2001). Menopause is the permanent cessation of the menses, identified retrospectively after one year without menses and occurs within this period of climacteric (Bernstein et al. 1996). Menopause may be naturally, artificially or prematurely induced (NIH, 2005).

There are many symptoms which are associated with this ageing period. Some of those symptoms include headaches, hot flushes, profuse sweating, sleeping problems, inability to concentrate, heart palpitations, nervousness, bone mass decrease, joint pain, feelings of vertigo and depressive moods (Bernstein et al. 1996 and Manson et al. 2001).

The climacteric period is a natural phenomenon in an ageing woman's life. But for many females this phase of life comes with many distressing and/or unpleasant symptoms. There are three options for treating menopausal symptoms. The first option is a life-style approach, which includes a healthy diet and regular exercise; the second option is an alternative approach, which includes homoeopathy, herbs and acupuncture; and the third option is an allopathic approach, which includes the use of Hormone Replacement Therapy (HRT). Women on HRT suffer from a number of side-effects, including headaches, irritability, breast tenderness, nausea, constipation and loss of libido (Walker et al. 2002), as well as the significant risks.

In this research study, homoeopathic complex remedies were prescribed to the participants. The participants were given two complexes to take for a period of eight weeks. The participants were randomly allocated to either an experimental or control group, and given sets of medication (Remedy or Placebo A and B). The participants took ten drops of Remedy A (R10® or placebo A) in the morning and ten drops Remedy B (R20® or placebo) at night.
IMPORTANCE OF THE PROBLEM

Modern society views menopause in a negative light, with emphasis on youth, beauty and sexuality. The symptoms that accompany this period make women feel old, ugly and as if they have lost their sexuality (Stoppard, 2001). The most important symptoms of the climacteric period are headaches, hot flushes, profuse sweating, sleeping problems, inability to concentrate, heart palpitations, nervousness, bone mass decrease, joint pain, feelings of vertigo and depressive moods (Bernstein et al. 1996 and Manson et al. 2001).

Even though the climacteric period is a normal ageing process, many women seek medical assistance to palliate these symptoms. Allopathic medication such as Hormone Replacement Therapy (HRT) is readily used for climacteric symptoms, but alternative treatments are often sought, as there are adverse side-effects and risks associated with HRT (Grady, 2006). Homoeopathy is one of the alternative treatment modalities used in treating climacteric symptoms.

1.2 HYPOTHESIS

Null hypothesis: Homoeopathic complex remedies are ineffective in alleviating climacteric symptoms
Hypothesis: It is hypothesized that homoeopathic complex remedies will alleviate climacteric symptoms.

1.3 PURPOSE OF THE STUDY

The aim of this research was to determine the efficacy of Dr Reckeweg R10® and R20® in treating climacteric symptoms.

1.4 ASSUMPTIONS

It is assumed that:
- Participants took the homoeopathic remedies in the prescribed manner.
- Participants did not take any other form of medication for the treatment of climacteric symptoms during the study.
Participants' subjective assessment of treatment progress were correct, honest and unbiased. Participants did not change their normal lifestyles, exercise routines or dietary habits immediately prior to, or during the study.

1.5 LIMITATIONS OF METHOD

The following variables were considered:

- Participants' abilities to take the prescribed homoeopathic remedies in the correct manner.
- Participants' honest and unprejudiced revealing of any changes in their symptoms.
CHAPTER TWO

REVIEW OF RELATED LITERATURE

2.1 INTRODUCTION

The word 'climacteric' was first used in 1827 by Hall to describe the 'change of life' (Wren and Nachtigall, 1996). The term climacteric comes from the Greek word klimakter meaning 'a critical phase' (Anderson, 1991). Climacteric is the period of waning ovarian function which signals the end of the female reproductive life-span, which can last 15-20 years (Bernstein et al. 1996). The median age at natural menopause is 51.3 years and the median age at the inception of the perimenopause is 47.5 years (Schneider and Naftolin, 2005). The climacteric period may range from age 35 to age 65 years in the female. Menopause comes from the Greek word menpausis meaning 'month stopping' (Agrawal, 1997). Menopause is the permanent cessation of the menses (NIH, 2005). It is established retrospectively when menses have not occurred for one year (Giampapa et al., 2004). Premature menopause is the permanent cessation of menstruation due to loss of ovarian follicular activities before the age of 40 years. Smokers experience an earlier natural menopause by at least one year (Stoppard, 2001).

The climacteric period is divided into four stages:

1. Premenopause: the phase when menstrual periods are irregular and/or heavy.
2. Perimenopause: a two year period, on either side of the last menstrual period.
3. Menopause: established twelve months after the last menstrual period.
4. Postmenopause: occurs after menopause and lasts until the end of a woman's life (Stoppard, 2001).

When the climacteric and menopause occur naturally, they are chronological and physiological events of a woman’s ageing process and not pathological conditions. There are many symptoms which characterise this ageing period. The most important symptoms of the climacteric period are headaches, hot flushes, profuse sweating, sleeping problems, inability to concentrate, heart palpitations, nervousness, bone mass decrease, joint pain, feelings of vertigo and depressive moods (Bernstein et al. 1996 and Manson et al. 2001). Many women
choose to use Hormone Replacement Therapy, however, it has been established that the side
effects and risks outweigh the benefits (NIH, 2005).

2.2 THE FEMALE REPRODUCTIVE SYSTEM

2.2.1 The Menstrual and Ovarian cycles

In the female, the production of ova begins before birth, accelerates at puberty, and ends at
menopause. At birth, the ovaries have approximately two million primordial follicles, both
containing a primary oocyte. But, at puberty, the number has dropped to about four hundred
thousand (Martini, 2001). Only 0.1 percent of the ova are ovulated, most are lost by atresia
(Guyton and Hall, 1997).

The hypothalamus produces Gonadotropin-releasing hormone (GnRH), which causes the
anterior pituitary gland to release follicle stimulating hormone (FSH) and luteinizing
hormone (LH). FSH stimulates the follicles to ripen and come to the surface of the ovary.
One of these ripened follicles reaches the surface first and the follicle wall ruptures and
releases the ovum. Then, ovulation has taken place and this is initiated by a high circulation
of LH. After ovulation, the follicle collapses to form the Corpus Luteum (CL). CL produces
Progesterone. Progesterone and Oestrogen have a negative feedback to the hypothalamus and
pituitary. They cause the level of both FSH and LH to fall (Rosenfeld, 1997; Anderson,

The first phase (days 0-14) of the menstrual cycle is dominated by oestrogen, and the
endometrium repairs itself following the previous menstruation. This is called the
proliferation phase. The second phase (days 15-28) of the cycle is dominated by
progesterone. The endometrium is full of glands and contains many blood vessels giving it a
rich blood supply. This is called the secretory phase (Rosenfeld, 1997).

If no fertilization occurs, the levels of oestrogen and progesterone fall, and can no longer
sustain the lush secretory endometrium. This leads to significant changes in the endometrium
causing ischaemia and myometrial hyperactivity. Spiral arterioles constrict, and endometrial
build up is then followed by a sloughing of the endometrial layer called the menses.
Prostaglandin milieu influences the volume of menstrual flow. A balance between Prostaglandins G2 and H2 (vasoconstriction and platelet aggregation respectively) and prostaglandins I2 (potent vasodilator), is required for appropriate control of menstrual flow (Anderson, 1991 and Rosenfeld, 1997).

2.2.2 The Functions of the Female Hormones

2.2.2.1 Oestrogen

Oestrogen hormone is synthesized mainly ovaries and in small quantities by the adrenal gland, corpus luteum and adipose tissue. During childhood, the secretion of oestrogen is very small, but following puberty, large quantities of oestradiol, the primary oestrogen during reproductive life, are secreted under the influence of the pituitary gonadotropic hormones (FSH and LH) (Martini, 2001).

The important functions of oestrogen include: stimulating bone and muscle growth; maintaining female secondary sex characteristics such as hair distribution; affecting central nervous system activity, especially in the hypothalamus where oestrogen increases sexual drive; maintaining functional accessory reproductive glands and organs; supporting the maturation of the oocytes; and initiating the repair and growth of the endometrium (Martini, 2001). Every organ in a woman's body is affected by oestrogen. When oestrogen levels drop, the organs reflect these changes (Stoppard, 2001).

2.2.2.2 Progesterone

Progesterone hormone is secreted by the corpus luteum after ovulation (Anderson, 1991). There is no progesterone in childhood, only from the time of puberty. Progesterone's main function is to promote the secretory changes in the endometrium, preparing the uterus for the implantation of the fertilized ovum. It also promotes the development of the embryo and foetus, and maintains the pregnancy (Guyton and Hall, 1997).
2.3 THE CLIMACTERIC

Climacteric is the period of waning ovarian function which signals the end of the female reproductive life-span. The climacteric can last 15-20 years (Bernstein et al. 1996). It can also be defined as the syndrome of endocrine, somatic and psychological changes occurring at the termination of the reproductive period in the female (Luciano et al. 2001). Menopause is the permanent cessation of the menses (Giampapa et al. 2004). Menopause is established when menses have not occurred for one year and may be naturally, artificially or prematurely induced (NIH, 2005).

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The median age at natural menopause is 51.3 years and the median age at the inception of the perimenopause is 47.5 years (Schneider and Naftolin, 2005). The climacteric period may range from age 35 to age 65 in the female life cycle. Premature menopause is the permanent cessation of menses before the age of 40 years. Smokers experience an earlier natural menopause by at least one year (Stoppard, 2001).

Perimenopause is a two year period on either side of the last menstrual period. It is a retrospective diagnosis, since it is only after the menses has stopped for a year, that you can measure backwards two years to when the perimenopause began (Stoppard, 2001). During this phase, women often have shorter menstrual cycles, and menopausal symptoms intensify. Towards the end of this phase, intervals of sixty days or more may occur between menstrual periods (Guidozzi, 2005).

2.3.1 Symptoms of Climacteric

There are many symptoms associated with the climacteric period. Approximately 10 to 20% of women experience discomfort severe enough to seek medical attention. Menopausal symptoms may differ among racial and ethnic groups (NIH, 2005). Women can expect to live a third to half of their adult life post-menopausally (Siple and Gordon, 2001). The symptoms of the climacteric range from vasomotor to psychological, locomotor and genitourinary symptoms. Vasomotor symptoms include hot flushes, light-headed feelings, headache, sleeplessness and unusual tiredness (Drife and Magowan, 2004).
Psychological and emotional symptoms include irritability, depression, anxiety and mood changes. Locomotor symptoms include backache, joint pains and muscle pains. Genitourinary symptoms include low libido, vaginal dryness and urinary frequency (Wren, 1996).

2.3.1.1 Vasomotor Symptoms

The prevalence of the vasomotor symptoms varies from 14 to 51% in the premenopause, from 35 to 50% in perimenopause, and from 30 to 80% postmenopausal. High body mass index and early onset of menopause are associated with more vasomotor symptoms (NIH, 2005).

Hot flushes can be defined as recurrent, transient and sudden feelings of heat, usually felt in the face, neck or chest. They can occur with varying severity and frequency, and may be accompanied by perspiration, increased heart rate, palpitations, irritability, anxiety or panic (Hickey et al, 2005). Twenty percent of women begin experiencing hot flushes while still menstruating regularly. Hot flushes slowly improve as the body adjusts to the new low oestrogen concentration, but in approximately 25% of women they continue for more than five years (Drife and Magowan, 2004).

Hot flushes that occur at night are called night sweats. Women who suffer from night sweats wake up hot and drenched in perspiration, and often have to change their night clothes. Sleeplessness is most commonly linked to night sweats in menopausal women (Stoppard, 2001).

2.3.1.2 Psychological and Emotional symptoms

Feelings such as anxiety, irritability, depression, lethargy, tearfulness and mood swings can occur at any age, but they rarely occur together or as frequently as they do during climacteric. These emotional changes may be due to the fact that a woman’s sleep is being interrupted by night sweats, as fatigue is one of the causes of irritability and anxiousness (Stoppard, 2001). These symptoms affect 8 to 37% of premenopausal women, 11 to 21% of perimenopausal women and 8 to 38% of postmenopausal women. A history of prior depression, life stress as well as general health status are the major predictors of mood symptoms in midlife. It is
difficult to establish whether menopause causes any increase in the prevalence of mood symptoms during the perimenopausal years. In cognitive disturbance, studies are inadequate for separating ageing effects from the effects of menopause (NIH, 2005).

2.3.1.3 Gynaecological and Urinary Symptoms

These symptoms are very common during the menopause (Stoppard, 2001). The prevalence of these symptoms is 7 to 39% in perimenopausal women (NIH, 2005). The frequency of the menstrual bleeding might decrease, followed by the absence of menstruation. However, many women experience heavier, more frequent, or prolonged menses before the onset of oligomenorrhoea (Berkow \textit{et al}, 1999). The urethra, vagina and bladder are oestrogen dependent and undergo gradual atrophy after menopause. Vaginal skin becomes thin causing dyspareunia and bleeding. Loss of vaginal glycogen causes a rise in pH which can predispose to local infection. These atrophic symptoms may appear years after menopause (Drife and Magowan, 2004). Other symptoms that may occur include pruritus vulvae, urinary frequency, dysuria, and urge and stress incontinence (Stoppard, 2001).

2.4 LONG TERM EFFECTS OF THE CLIMACTERIC

2.4.1 Cardiovascular Disease

The risk of heart disease is significantly increased in postmenopausal women. The use of oestrogen therapy may reduce the risk of heart disease after menopause by 50% (Berkow \textit{et al}, 1999). Cardiovascular disease is considered to be the leading cause of death in post menopausal women in the USA and UK. It accounts for about 17% of all women, 27% of whom are under the age of 75 years. The main forms of the disease are coronary heart disease (CHD) and stroke.

Natural oestrogen is cardioprotective, and during menopause the incidence of CHD increases gradually with age (Manassiev \textit{et al}, 2004).

The risk factors for increased cardiovascular disease include family history, age, high LDL cholesterol and triglyceride levels, smoking, obesity, hypertension, diabetes mellitus, sedentary lifestyle, high alcohol intake, and diet (Love and Lindsey, 1997).
2.4.2. Osteoporosis

Osteoporosis is the most prevalent metabolic bone disease in developed countries, and it is defined as a systemic skeletal disease characterized by low bone mass and deterioration of bone tissue with a consequent increase in bone fragility and susceptibility to non-traumatic fracture. Osteoporosis has to be considered a multifactorial disease in which genetic determinants are modulated by hormonal, environmental and nutritional factors (Lobo et al, 2002).

During the first four years after menopause, there is an annual loss of 1-3% of bone mass, falling to 0.6% per year after that (Drife and Magowan, 2004). This increases the risk of bone fractures which occur in one in three women by age 70. Progesterone stimulates osteoblast activity which builds new bone. Taking progesterone (four times more than oestrogen) increases bone density. So according to Holford it is the relative excess of oestrogen to progesterone which causes osteoporosis.

2.5 MANAGEMENT OF THE CLIMACTERIC

2.5.1 Hormone Replacement Therapy

Although menopause is a natural process, the symptoms that accompany it force women to seek medical help. After menopause, the ovaries no longer produce enough oestrogen and progesterone. A lack of those two hormones results in increased activity of the GnRH center. Heightened GnRH activity activates the vasomotor center causing hot flushes and perspiration. Oestrogen drops by 40 to 60% at menopause, while progesterone levels can drop to zero. The presence of oestrogen makes body target tissues more sensitive to progesterone, and the presence of progesterone does the same for oestrogen. Progesterone has an opposing, or balancing effect on oestrogen. When progesterone drops to nearly zero, oestrogen dominance results which causes a long list of unpleasant symptoms (Lee and Hopkin, 2004). Allopathic treatment has been the treatment of choice. It uses a method called hormone replacement therapy (HRT). The conventional HRT suits some women and 70% stop within a year of starting it, usually due to unpleasant symptoms or a lack of results (Holford, 1997). There is a diverse range of HRT products, and a number of ways in which
they can be administered. HRT may be administered orally, transdermally, vaginally and via implants. The most common and convenient way is oral (Stoppard, 2001).

2.5.1.1 Risk of Hormone Replacement therapy

The risks of HRT outweigh the benefits as proved by the Women's Health Initiative study, whereby 16 608 postmenopausal women aged between 50 to 70 years enrolled. The study used combined oestrogen and progesterone (HRT). It was discontinued after five years as the health risks exceeded the benefits. Here are some of the findings: HRT does not reverse the established CHD or prevent CHD in otherwise healthy females; it increases the risk of myocardial infarction, deep venous thrombosis and thromboembolism, especially in the first year of treatment; and it slightly increases invasive breast cancer. It appears that HRT provides a growth-promoting role in the breast cancer, rather than playing a causative role. This increased risk is worse in women taking both oestrogen and progesterone (NIH, 2005).

In women who have a uterus, the risk of uterine cancer increases by seven times when oestrogen is used alone. The combination of oestrogen and progesterone decreases this risk (Beers and Berkow, 1999). The combined HRT also decreases the incidence of bone fracture due to osteoporosis, and colorectal cancer (NIH, 2005).

2.5.1.2 Contraindications for Hormone Replacement Therapy

The contraindications for HRT are pregnancy, undiagnosed vaginal bleeding, undiagnosed breast mass, history of breast cancer, breast feeding, cardiovascular disease, thromboembolic disorders and uterine mass or cancer (Manassiev et al, 2004).

Oral therapy is avoided in conditions with gastrointestinal and hepatic malfunctions, alcohol abuse, risk of gall stone formation, as well as lactose intolerance (Lobo et al, 2002).

2.5.1.3 Side Effects of Hormone Replacement Therapy

More women discontinue HRT because of side effects than because of complications. Side effects of HRT include breast tenderness, leg cramps, headaches, weight gain, bloating, nausea, backache, depression, moodiness, irritability, fluid retention, acne, greasy skin, and loss of libido (Wren and Nachtigall, 1996; Stoppard, 2001). Irregular bleeding may occur at
the beginning of HRT, but this eventually stops. Irregular bleeding may also be caused by thyroid disease, chronic liver disease, chronic renal disease, diabetes, Cushing’s disease and autoimmune disease (Rosenfeld, 1997; Beers and Berkow, 1999).

2.5.2 Alternative treatment

Due to the side effects of HRT, many women discontinue treatment within a year and seek alternative treatments (Holford, 1997). These include: homoeopathy, naturopathy, herbal medicine, chinese medicine and many more.

2.5.2.1 Naturopathy

Naturopathy sees the menopause as a time of increased stress for the whole person, and uses several approaches such as improved nutrition, exercise, relaxation, and specific treatments such as acupuncture to improve hormone regulation (Wren and Nachtigall, 1996). ‘Optimum nutrition’ can alleviate many symptoms and/or shorten their duration. Supplementation with vitamin D, E and B complex, calcium, magnesium and zinc is also recommended, as well as the use of essential fatty acids like evening primrose oil (Holford, 1997). Dietary changes include avoidance of saturated fats, sugar, excessive alcohol, caffeine and smoking (Giampapa et al., 2004, Wren and Nachtigall, 1996).

Exercise increases cardiorespiratory function, and improves moods and reduces depression. It reduces the risk of osteoporosis. It also lowers the risk of cardiovascular disease, diabetes, headaches and improves sleep (Giampapa et al. 2004).

Relaxation alleviates the symptoms of menopause by decreasing irritability and aggressiveness, while increasing energy levels (Stoppard, 2001).

2.5.2.2 Herbal Medicine

Herbs are very useful in the treatment of menopausal symptoms. The most common ones for menopause are:

- *Vitex agnus castus*, to balance the hormones
- *Leonurus cardiac*, to reduce anxiety
- *Chamaelirum luteum*, which has a hormonal and digestive benefit
• *Glycorrhiza glabra* for oestrogen enhancement

• *Cimicifuga racemosa*, for oestrogen enhancement

• *Salvia officinalis* for decreasing sweating and hot flushes

• *Hypericum perforatum* which has antidepressant and antiviral effects

• Other herbs used in the treatment of the menopause are *Panax quinquefolium, Avena sativa, Virbunam opulus* and *Evening primrose* (Wren and Nachtigall, 1996).

2.6 HOMOEOPATHY

2.6.1 Homoeopathic Principles

Homoeopathy is a form of medicine that involves the use of specially prepared and diluted medicinal substances. The term 'homoeopathy' is derived from the Greek word *homoios*, meaning 'like', and *pathos*, meaning 'suffering'. The fundamental principle 'like cures like' or 'similia similibus curentur' is that a substance that causes symptoms in a healthy person can, when those same symptoms occur in a sick person, help cure that patient by eliminating the disease (Downey, 1997). It is a form of medicine which stimulates the body's own healing mechanism to reinstate health and well-being (Treacher, 2000). Medications are diluted and potentised, with no known side-effects except a possible minor initial aggravation of existing symptoms (Jouanny, 1994).

The Vital Force is the natural defence mechanism of the body and responds when the body is in a diseased state (Vithoulkas, 1993).

Minimum dose is the smallest dose possible to elicit a response from the Vital Force. It is believed that small doses have a stimulant effect, larger doses induce a more direct primary effect, and massive doses are toxic (Close, 1996; Koehler, 1986).
2.6.2 Homoeopathic Prescription

Homoeopathic medication is prescribed to act in the same way as the reactive mode of the organism and defence mechanism, thus in cooperation with them. Homoeopathy stimulates the organism and defence mechanisms to make them more efficient (Crapanne et al, 1999). The patient determines the appropriateness of a stimulus by the nature of his response (Koehler, 1986). In classical homoeopathy, a single remedy is used at a time, but frequently today combination preparations of homoeopathic remedies are used (MacEoin, 1997). Complex homoeopathic prescribing uses mixtures of homoeopathic medicines used for specific symptoms or diseases and they are frequently prescribed over the counter (OTC) (Ernst and Hahn, 1998).

2.6.3 Treatment with Dr. Reckeweg R10® (Klimakteran) and R20® (Euglandin-F)

Dr Reckeweg & Company (Pty) Ltd. was founded in 1949. Based on the Homoeopathic principle of proving on remedy in healthy people, Dr Reckeweg Homoeopathic complexes were developed. They are strictly manufactured in accordance with the German Homoeopathic Pharmacopoeia. Dr Reckeweg & Company (Pty) Ltd. now supplies its products to over 40 countries world wide (Reckeweg, 2008).

2.6.3.1 Dr. Reckeweg R10® (Klimakteran)

R10® is a complex remedy preparation made from remedies prepared according to German Homoeopathic Pharmacopoeia. All the remedies in the complex remedy are homeopathically indicated for climacteric symptoms. It contains these remedies:

- Sulphuric acid D4
- Cimicifuga D4
- Lachesis D12
- Sanguinaria D4
- **Sepia** D4

*Sulphuric acid* D4 - is indicated for hot flushes followed by perspiration, easy bruising and heavy menses.

*Cimicifuga* D4 - is indicated for hot flushes, backache, nervousness, depression and sleeplessness.

*Lachesis* D12 - is indicated for hot flushes, palpitation and headaches.

*Sanguinaria* D4 - is indicated for hot flushes, irritation, rheumatic joint pains, sleeplessness, inability to concentrate and headaches.

*Sepia* D4 - is indicated for profuse sweating, fatigue, sleeplessness, depressive moods, backache and irritability (Phatak, 1982, Reckeweg, 2004 and Vermeulen, 1997).

### 2.6.3.2 Dr Reckeweg R20® (Euglandin-F®)

R20® is a complex remedy preparation made from remedies prepared according to German Homoeopathic Pharmacopoeia. All the remedies in the complex remedy are homeopathically indicated for support, stimulation and regulation of the endocrine system in females. It contains these remedies:

- **Glandulae suprarenales** D12
- **Hypophysis** D12
- **Pancreas** D12
- **Glandulae thyme** D12
- **Thyroidinum** D12
- **Ovaria** D12

*Glandulae suprarenales* D12 - indicated for aesthenia, weight reduction and myaesthesia. Hypertonia versus hypotonia.

*Hypophysis* D12 – has an antidiuretic effect and is the essential element of the hormonal system.

*Pancreas* D12 – it stimulates the secretion of digestive hormones.
Glandulae thymi D12 – indicated in exhaustion and mongolism.

Thyroidinum D12 - regulates the thyroid gland. Helps in myxoedema and helps drain the organism. Also indicated in intellectual development.

Ovaria D12 – it supports, stimulates and regulates the endocrine system in females (Reckeweg, 2004, Boericke, 2002 and Vermeulen, 1997).

2.7 HOMOEOPATHY AND THE CLIMACTERIC

Homoeopathy may play a positive role in menopause by supporting women through this life changing period. Successful treatment may prevent long term use of HRT. By opting for this approach, women will avoid the undesirable side-effects of HRT (MacEoin, 1997).

The following studies have been conducted at the University of Johnnesburg (formerly known as Technikon Witwatersrand):

- The Effect of Agnus Castus D3 on Menopausal Symptoms. This research trial concluded that Agnus Castus D3 is not effective in alleviating the symptoms of menopause when used in the short term (Lazarus, et al 2001).

- The Efficacy of Sepia® in the Management of Climacteric Symptoms. The results of this trial showed that the Homoeopathic complex remedy, Sepia®, did not produce a statistically significant improvement in climacteric symptom hot flushes, however in the first month there was an improvement in menstrual irregularity, recurrent cystitis and diffuse body pains. In the second month there was an improvement in night sweats, perspiration, weight gain, mood swings, irritability and depression, when compared to a placebo group (Compere, et al 2002).

- Homoeopathic Similimum Treatment of Secondary Insomnia in Pre- and Postmenopausal Women. This study showed that Homoeopathic similimum treatment has the potential to ameliorate the symptoms of insomnia (Pellow, et al 2002).

- A Comparative Study Between Femolene Ultra® and Klimakt-Heel® in the Management of Typical Climacteric Symptoms. In this study, patients using Femolene Ultra® (a phytotherapeutic product) and Klimakt-Heel® (a Homoeopathic product)
demonstrated a significant improvement in typical climacteric symptoms such as hot flushes and sleeping problems. But, Femolene Ultra® had a greater ameliorating effect on a larger number of participants (Penny, et al 2004).

- The Effect of the Homoeopathic Similimum in the Treatment of Climacteric Symptoms. The results of this research study showed that treatment with the homoeopathic similimum had a statistically significant effect on climacteric symptoms, sense of well-being, and energy levels (Artemi, et al 2004).

- The Efficacy of R59® in Weight Loss of Climacteric and Menopausal Women. This study concluded that R59® achieved results that were statistically insignificant for the period of trial. However mild improvement was observed by the researcher in weight and circumference body measurement reductions (Leite and Saunders 2006).

- The efficacy of the Homoeopathic Similimum in the Treatment of Climacteric Symptoms. In this three month research period, the participants demonstrated a clinically significant improvement of their climacteric symptoms. Only six of the ten symptoms showed statistically significant improvement, which could be due to the fact that there was too little data, and not all the participants experienced all symptoms (Bengis and Peck 2006).
CHAPTER THREE
MATERIALS AND METHODS

3.1 STUDY DESIGN

The methodology and Ethics were accepted by Higher Degrees Committee and Academic Ethics Committee on the 25 August 2008 (Ethical clearance no: 40/08). The researcher recruited thirty two females aged between 40 and 60, who were experiencing climacteric symptoms. This was a double blind study, with two groups: the first group was given two Homeopathic complexes, and the second group was given identically presented placebos. Both were packaged by the manufacturer who numbered them and only after the trial did the researcher find out who was on the experimental or placebo group. Volunteers read and signed the patient information and consent form (Appendix B).

3.2 RECRUITMENT OF PARTICIPANTS

Volunteers were recruited through advertisements (Appendix A), which were placed at University of Johannesburg (UJ) campuses and health facilities around Johannesburg. The volunteers had an initial consultation with the researcher who took a case history and performed a basic examination (Appendix C), which included vital signs, primary survey and the history of menopausal symptoms. Thirty two volunteers were selected to take part in the study. The volunteers were selected using the following criteria:

Inclusion criteria
- Volunteers were female and between the age of forty and sixty years.
- Volunteers were perimenopausal, with climacteric symptoms.
- Volunteers who had discontinued hormone replacement therapy or any other medical treatment for climacteric symptoms at least three months prior to enrolment were included in the study.

Exclusion criteria
- Volunteers were excluded if the perimenopause or menopause was surgically or
artificially induced, e.g. bilateral oophorectomy or total hysterectomy, any irradiation, chemotherapy, drug treatment, or other process that may have resulted in menopausal symptoms.

- Volunteers were excluded if they were on hormone replacement therapy or other allopathic medication for menopausal symptoms, phyto-therapy including phyto-hormones, and/or large doses of supplements.

- Volunteers were excluded if their climacteric symptoms started before the age of forty.

3.3 RESEARCH PROCEDURES

The participants were chosen using the inclusion and exclusion criteria. At the first consultation, each participant was informed of the requirements of the study, and they were required to complete the patient information and consent form (Appendix B). The participant's full case history was taken and a physical examination conducted. Then, the abbreviated Kupperman Menopause Index (Appendix E) was completed with the aid of the researcher. The participants were required to participate in the study for a period of twelve weeks. The abbreviated KMI was completed on a weekly basis and the average monthly score was recorded on the main Kupperman Menopause Index (Appendix F). The medication and placebo supply was for eight weeks, and was given during this first consultation. Participants were randomly allocated into group A (Medication) or group B (Placebo). They were divided into two matched groups based on age and severity of the menopausal symptoms determined by the KMI (Kupperman Menopause Index) score.

The second, third and fourth consultations took place at four, eight and twelve weeks respectively after the initial consultation. At each subsequent consultation, the completed abbreviated KMI scores were collected and averaged to make up the main KMI score. A follow-up case history was taken and a physical examination performed.

3.4 REMEDY ADMINISTRATION

DR RECKEWEG R10® and R20® were dispensed in 30ml bottles, together with identically presented placebos, and were given to group A and group B respectively to take for a period of eight weeks. The bottles were coded by Dr Reckeweg & Co. and disclosed at the end of
the study. The medication was given to the participants on their first consultation, and they took 10 drops of remedy A (R10® or placebo) in the morning and 10 drops of remedy B (R20® or placebo) at night.

3.5 TOOLS UTILISED

3.5.1 Kupperman Menopause Index

The KMI (Appendix F) was used as a subjective tool in the study. The KMI has been widely used in menopause research for many years. The menopause index was introduced by H.S. Kupperman, MHG Blatt and BB Wetchler in 1959 (Kupperman et al, 1959). The index allows the participant to score their climacteric symptoms. KMI evaluates ten symptoms:

1. Hot flushes
2. Profuse sweating
3. Sleeping problems
4. Nervousness/irritability
5. Depressive moods
6. Feeling of vertigo
7. Inability to concentrate
8. Joint pain
9. Headache
10. Heart palpitations

Each participant was requested to grade the severity of her symptoms as follows:

1. Not present...........0
2. Mild.....................1
3. Moderate...............2
4. Severe...................3

After grading the symptoms, they are multiplied by the constant. Common climacteric symptoms have a high constant value. The total value for the KMI was determined by adding the resulting values for each symptom. The KMI thus gave an indication of the severity of the climacteric symptoms, as experienced by each participant. The severity of the index was categorised as follows:

1. >35...............severe
2. 20-35...............moderate
3. 15-20.............mild
4. <15..............favourable therapeutic result

Therefore, the KMI allowed each participant to quantitatively record the way she was experiencing the climacteric symptoms. The abbreviated KMI was completed thirteen times throughout the study: once at first consultation, before treatment and then weekly until the trial was completed. The completed abbreviated KMI was collected during the monthly consultations. They were summed up and the average transferred to the main KMI.

Table 3.1 on the following page illustrates the constant, participant’s score and the total score indicating an overall measure of discomfort for the three month duration of the study. There are four columns: the first column is the name of the symptom, the second column is the constant, the third column is the participant’s score, and the fourth column is the result from the multiplication of the constant and the participant’s score. The total value indicating an overall measure of discomfort is at the bottom of the table.
Table 3.1: An example of the Kupperman Menopause Index illustrating how severity scores are added for each participant

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Constant</th>
<th>Before Treatment</th>
<th>First Month</th>
<th>Second Month</th>
<th>After Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hot flushes</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Profuse sweating</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Sleeping problems</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Nervousness/irritability</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Depressive moods</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Feeling of vertigo</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Inability to concentrate</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Joint pain</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Headache</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Heart palpitations</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>15</strong></td>
<td><strong>29</strong></td>
<td><strong>12</strong></td>
<td><strong>22</strong></td>
<td><strong>10</strong></td>
</tr>
</tbody>
</table>


3.6 RELIABILITY AND VALIDITY MEASURES

Medication was manufactured by the Dr Reckeweg and Company (Pty) Ltd. who manufacture according to the established German Pharmacopoeia. The participants were asked to indicate on the calendar should they forget to take their medication. They were also asked to take note of any other medication used during the trial period. The symptoms of the participants were measured using the KMI. The KMI has been in use since 1959. The KMI is a generally accepted scale commonly used to evaluate the climacteric symptoms. The researcher evaluated the participants monthly. The validity of this research relied on the honesty of the participants.

3.7 DATA COLLECTION

Three questionnaires were used for collection and analysis of data: the patient profile and case history (Appendix C), followed by the abbreviated KMI (Appendix E) and lastly the main KMI (Appendix F). The case history was taken at the beginning of the trial, and at the end of the first, second and third months. This was to monitor the participants' vital signs. The abbreviated KMI was completed weekly and the average of the four abbreviated KMI scores was transferred to the main KMI as a monthly score.

3.8 DATA ANALYSIS

Data collected from the participants using the abbreviated KMI (Appendix E) was analysed by the researcher with the assistance of a statistician. The data was analysed using Frequencies, Normality, Mann-Whitney test, Friedman test, Chi-squared test, Wilcoxon sign ranked test and the Bonferroni adjustment/correction test (Smith, 2010).
CHAPTER FOUR

RESULTS

4.1 INTRODUCTION TO RESULTS

Hypothesis: It was hypothesized that homoeopathic complexes Dr Reckeweg R10® and R20® would alleviate climacteric symptoms.

The abbreviated KMI (Appendix E) was used to evaluate each participant's personal opinion about her symptoms. Each participant was required to complete the abbreviated KMI thirteen times during the course of the study: once at the initial consultation, and then weekly for twelve weeks. The index required the participants to score the severity of their climacteric symptoms on a scale of 0 to 3 (where 0 indicated that the symptom was not present, and 3 indicated that the symptom was severe).

4.2 STATISTICAL RESULTS

4.2.1 Group frequency

Thirty-two participants were recruited to participate in the research study. Participants in the study were recruited based on the inclusion and exclusion criteria. Participants were allocated to either the experimental or placebo group by the double-blind method.

<table>
<thead>
<tr>
<th>Group</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td>16</td>
<td>50.0</td>
</tr>
<tr>
<td>Placebo</td>
<td>16</td>
<td>50.0</td>
</tr>
<tr>
<td>Total</td>
<td>32</td>
<td>100.0</td>
</tr>
</tbody>
</table>
4.2.2 Test for Normality

![Figure 4.0: A bell curve](https://www.robertniles.com/statstable.html)

This bell curve shows that the research group was normally distributed with the P-value $\geq 0.05$. A bell curve with a P-value $< 0.05$ means the research group is not normally distributed. For this study, the group was normally distributed (P-value $\geq 0.05$) as would be evident in the table and charts below (Smith, 2010).

Using the Shapiro-Wilk test, the table below shows that the symptoms in the groups were normally distributed before treatment (Month_0). The symptoms continued to be normally distributed during the first month, however during the second month they were only normally distributed in the medication group. This is because the symptoms were decreasing in severity due to the effect of the medication. After treatment, the symptoms were normally distributed.

Table 4.1 Test for Normality (using Shapiro-Wilk Test)

<table>
<thead>
<tr>
<th>Group</th>
<th>Shapiro-Wilk</th>
<th>Statistic</th>
<th>df</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total_0</td>
<td>Medication</td>
<td>.961</td>
<td>16</td>
<td>.684</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>.932</td>
<td>16</td>
<td>.258</td>
</tr>
<tr>
<td>Total_1</td>
<td>Medication</td>
<td>.946</td>
<td>14</td>
<td>.505</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>.922</td>
<td>15</td>
<td>.207</td>
</tr>
<tr>
<td>Total_2</td>
<td>Medication</td>
<td>.862</td>
<td>14</td>
<td>.032</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>.912</td>
<td>12</td>
<td>.229</td>
</tr>
<tr>
<td>Total_3</td>
<td>Medication</td>
<td>.889</td>
<td>14</td>
<td>.078</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>.883</td>
<td>12</td>
<td>.094</td>
</tr>
</tbody>
</table>
The p-values above can be displayed in Box-Whisker charts below, for months zero, one, two, and after treatment.

Figure 4.1 Box-plot for month zero (Before treatment)

Medication group: Statistics = 0.961; df (variables) = 16; Sig (P-value) = 0.684
Placebo group: Statistics = 0.932; df = 16; Sig = 0.258

Before treatment, it is evident that the data was normally distributed with p-value = 0.684 for the medication group and p-value = 0.258 for the placebo group.
During the first month, variables for the medication group decreased by two, and for the placebo group by one. The p-value of both the medication and placebo groups decreased, but the data remained normally distributed.
Medication group: Statistics = 0.862; df = 14; Sig = 0.032
Placebo group: Statistics = 0.912; df = 12; Sig = 0.229

During the second month, the variable for the medication group remained the same, while the variables for the placebo group decreased by three. The p-value of the medication group went below 0.05, but the Box-plot still depicts a normal distributed data. The data is acceptable because it is assumed that the changes are due to the effect of the medication.
After the treatment, the variables for both the medication and placebo groups remained the same. The p-value of the medication group exceeded 0.05, which indicates a normal distribution, and the data for the placebo group retained a normal distribution as well.
4.2.3 Comparisons between Groups (Inter Group)

Mann-Whitney Test (Non-Parametric test) Tables

Table 4.2 Mean and Mean Rank

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Mean Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td>16</td>
<td>28.44</td>
<td>9.612</td>
<td>17.94</td>
</tr>
<tr>
<td>Placebo</td>
<td>16</td>
<td>25.44</td>
<td>10.942</td>
<td>15.06</td>
</tr>
<tr>
<td>Total 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td>14</td>
<td>20.71</td>
<td>9.603</td>
<td>13.82</td>
</tr>
<tr>
<td>Placebo</td>
<td>15</td>
<td>23.47</td>
<td>8.733</td>
<td>16.10</td>
</tr>
<tr>
<td>Total 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td>14</td>
<td>14.50</td>
<td>8.916</td>
<td>9.11</td>
</tr>
<tr>
<td>Placebo</td>
<td>12</td>
<td>27.25</td>
<td>7.864</td>
<td>18.63</td>
</tr>
<tr>
<td>Total 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td>14</td>
<td>15.21</td>
<td>8.088</td>
<td>9.11</td>
</tr>
<tr>
<td>Placebo</td>
<td>12</td>
<td>27.83</td>
<td>7.602</td>
<td>18.63</td>
</tr>
</tbody>
</table>

Table 4.3 Mann-Whitney U, Z and p

<table>
<thead>
<tr>
<th>Month</th>
<th>Mann-Whitney U</th>
<th>Wilcoxon W</th>
<th>Z</th>
<th>Asymp. Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total 0</td>
<td>105.000</td>
<td>241.000</td>
<td>-.868</td>
<td>.385</td>
</tr>
<tr>
<td>Total 1</td>
<td>88.500</td>
<td>193.500</td>
<td>-.722</td>
<td>.470</td>
</tr>
<tr>
<td>Total 2</td>
<td>22.500</td>
<td>127.500</td>
<td>3.169</td>
<td>.002</td>
</tr>
<tr>
<td>Total 3</td>
<td>22.500</td>
<td>127.500</td>
<td>3.167</td>
<td>.002</td>
</tr>
</tbody>
</table>

Mann-Whitney test was done to determine if there was a difference between the medication and the placebo group. If there is a difference the p-value will be $p < 0.05$, and if there is no difference, $p \geq 0.05$. Mann-Whitney test was done to establish the difference between the medication and placebo groups, and to continue measuring this difference before, during and after the treatment. Mann-Whitney test analysis revealed a significant difference between medication and placebo groups in
their ranking of the symptoms. As proposed, the sum of the average ranks of the placebo group was significantly different ($M_{\text{rank}} = 18.63, n = 12$) compared to the sum of the average ranks of the medication group ($M_{\text{rank}} = 9.11, n = 14$) $z(26) = -3.167, p<0.05$.

4.2.4 Intra-group comparison over time

Table 4.4 Friedman Test (Non-Parametric Test)

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Mean Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total_0</td>
<td>14</td>
<td>29.36</td>
<td>9.162</td>
<td>4.00</td>
</tr>
<tr>
<td>Total_1</td>
<td>14</td>
<td>20.71</td>
<td>9.603</td>
<td>2.71</td>
</tr>
<tr>
<td>Total_2</td>
<td>14</td>
<td>14.50</td>
<td>8.916</td>
<td>1.61</td>
</tr>
<tr>
<td>Total_3</td>
<td>14</td>
<td>15.21</td>
<td>8.088</td>
<td>1.68</td>
</tr>
<tr>
<td>Placebo</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total_0</td>
<td>12</td>
<td>26.00</td>
<td>10.027</td>
<td>2.58</td>
</tr>
<tr>
<td>Total_1</td>
<td>12</td>
<td>24.17</td>
<td>8.922</td>
<td>1.79</td>
</tr>
<tr>
<td>Total_2</td>
<td>12</td>
<td>27.25</td>
<td>7.864</td>
<td>2.67</td>
</tr>
<tr>
<td>Total_3</td>
<td>12</td>
<td>27.83</td>
<td>7.602</td>
<td>2.96</td>
</tr>
</tbody>
</table>

Table 4.5 Friedman's Chi-Square Test

<table>
<thead>
<tr>
<th>Medication</th>
<th>N</th>
<th>Chi-square</th>
<th>df</th>
<th>Asymp. Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>14</td>
<td>32.343</td>
<td>3</td>
<td>.000</td>
</tr>
<tr>
<td>Placebo</td>
<td>12</td>
<td>5.759</td>
<td>3</td>
<td>.124</td>
</tr>
</tbody>
</table>

Table 4.5 presents the median usefulness rank of the total symptoms in each group. Using Friedman's chi-square test (table 4.6), we found a significant difference in the rankings of the symptoms both in the medication group, $X_r^2(3, N = 14) = 32.343, p < 0.0005$, and placebo group, $X_r^2(3, N = 12) = 5.759, p \geq 0.0005$. 

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4.2.5 Paired Comparisons

Wilcoxon Signed-Rank Test (Non-Parametric Test)

Wilcoxon Signed-Rank test (Appendix G) was done to see where the difference over time is. It compares the mean and standard deviation of the first, second and third months of treatment against month zero. It was only done on the medication group because it is the one which had a difference.

4.2.6 Bonferroni adjustment/correction

The p-value (0.05) is made stricter by dividing it by one, two and three. Then, we tested the biggest p-value against the answer from the division by one. Thereafter we did the same for division by two and three. If any of the p-values are larger than indicated, it shows no difference over time period. P-values of the first, second and third month are tested against the baseline (p-value before treatment). Refer to the table on the next page.
Table 4.6 Bonferroni adjustment

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Group Medication</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Asymp. Sig. (2-tailed)</td>
</tr>
<tr>
<td>HotFlushes_1 - HotFlushes_0</td>
<td>-2.961&lt;sup&gt;a&lt;/sup&gt;</td>
<td>.003</td>
</tr>
<tr>
<td>HotFlushes_2 - HotFlushes_0</td>
<td>-3.191&lt;sup&gt;a&lt;/sup&gt;</td>
<td>.001</td>
</tr>
<tr>
<td>HotFlushes_3 - HotFlushes_0</td>
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<td>-3.297&lt;sup&gt;a&lt;/sup&gt;</td>
<td>.001</td>
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</table>

Test the smallest p-value of each symptom against a significance level of 0.05 / 3 = 0.0167
Test the 2nd smallest p-value of each symptom against a significance level of 0.05 / 2 = 0.025
Test the largest p-value of each symptom against a significance level of 0.05 / 1 = 0.05
CHAPTER FIVE

DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 DISCUSSION

Thirty two female participants were recruited for this double blind study and divided into medication and placebo groups. Six participants did not complete the trial for unknown reasons. At the end of the study, in the medication group there were 14 participants, and in the placebo group there were 12 participants.

The Kupperman Menopause Index (Appendix F) was used to evaluate each participant's personal opinion about her symptoms. Participants completed the abbreviated Kupperman Menopause Index (Appendix E) thirteen times during the course of the trial period: first at the initial consultation, and then weekly for twelve weeks. Four abbreviated KMI scores were averaged to monthly scores and then transferred to the main KMI, which was statistically analysed.

The data was analysed using Shapiro-Wilk test, Mann-Whitney test, Friedman test, Chi-square test, Wilcoxon signed-ranked test and Bonferroni adjustment test:

1. Shapiro-Wilk test: showed that the data was normally distributed from the beginning to the end of the trial. It was shown or displayed by Box-plot graphs.
2. Mann-Whitney test: showed statistically significant improvement on hot flushes, sleeping problem, nervousness/irritability, depressive moods, concentration and heart palpitations. Overall, there was no improvement (not statistically significant) during the first month. However during the second and third months the improvement was statistically significant.
3. Friedman test and Chi-square test: showed that all symptoms improved significantly, clinically and statistically.
4. Wilcoxon signed-ranked test: showed that nine symptoms improved significantly, except feelings of vertigo, which showed no statistically significantly improvement.
5. Bonferroni adjustment/correction: showed that nine symptoms improved significantly, except joint pain, which showed no statistically significantly improvement.

5.2 CONCLUSION

Overall the results for this research trial were statistically significant. Dr Reckeweg R10\textsuperscript{®} and R20\textsuperscript{®} were found to be helpful in alleviating the climacteric symptoms and therefore the null hypothesis is rejected and the working hypothesis is accepted. The improvement of the symptoms started to show clinically in the first four weeks even though the tests (statistics) started to show them only in the second month of the trial. Even though six participants did not finish the trial, the study was a success, and it would be justifiable to do more Homoeopathic studies for a longer period with larger samples to ascertain the long-term benefits and side effects.

5.3 RECOMMENDATIONS

Based on the results of this research study, it is recommended that further studies be done so that:

- The effect of the long term use of homoeopathic complexes can be established;
- We can compare complex remedies to similimum remedies;
- We can compare homoeopathic treatment to other alternative treatments;
- The trial can be performed in one season only, to decrease the influence of environmental temperatures on hot flushes and night sweats;
- Continue using the Kupperman Menopause Index in future studies as it was very useful in monitoring the progress of the climacteric symptoms in this study and will allow for interstudy comparison.
REFERENCES


Mehta, DK, Martin, J (2004). *British Medical Formulary.* Published by British Medical Association and Royal Pharmaceutical Society, Oxford. p 357.


Rosenfeld, J (1997). *Women’s Health in Primary Care.* Published by Williams and Wilkins. pp 422-425.


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MENOPAUSE!!!

DO YOU SUFFER FROM THE FOLLOWING

HOT FLUSHES, PROFUSE SWEATING, SLEEPING DISTURBANCES, IRRITABILITY, DEPRESSIVE MOODS, FEELING OF VERTIGO, INABILITY OF CONCENTRATION, JOINT PAIN, HEADACHE, HEART PALPITATION.

If you are between the ages of 40 and 60 years old and suffering from Menopausal symptoms, you may qualify to participate in a Research Study being conducted through the Department of Homoeopathy at the University of Johannesburg on

The efficacy of the Homoeopathic complexes Dr Reckeweg R10° and R20° in the treatment of symptoms of the Menopause.

Ethical Clearance Number: 40/08

This study is being conducted at the University of Johannesburg's Homoeopathic Health Clinic. Participation is voluntary and strictly confidential.

If you qualify to take part in this study Consultation and treatment are FREE OF CHARGE!!!

For more information, please contact

Charles Muila
0728915055
APPENDIX B

PATIENT INFORMATION AND CONSENT FORM

The efficacy of the Homoeopathic Complexes Dr Reckeweg R10® and R20® in the treatment of menopausal symptoms

Dear Participant

I am Charles Muila, a final year M Tech Homoeopathic student of the Faculty of Health Sciences, University of Johannesburg. I am inviting you to participate in my research study in completion of my masters degree.

The aim of the study is to determine the efficacy of Dr. Reckeweg R10® and R20® in treating menopausal symptoms. If you are between 40 and 60 years of age and experiencing menopausal symptoms, you are invited to take part in this study. The treatment will be free of charge, and you are requested to participate in the study for three consecutive months.

All volunteers will be requested to complete a patient profile and case history, with the help of the researcher, in order to select suitable participants for the study. As a participant, you will be randomly allocated to either a control group or a trial group (which means, you may get the medication or the placebo containing no active medication. Neither you nor the researcher will know if you are on medication or placebo until after the study is completed). You are requested to complete the abbreviated Kupperman Menopause Index weekly, to analyse any changes experienced by the participant throughout the trial period.

To the best of the researcher's knowledge, there are no risks anticipated in this study. Any problems arising during the study should immediately be brought to the researcher or the supervisor's attention, and you will be appropriately referred. Contact details of both the researcher and the supervisor are given below.
Taking part in this study is voluntary and you are free to withdraw your consent at any time, and discontinue your participation. Your privacy will be protected by ensuring that all the records are kept confidential.

The potential benefit for the participants is an improvement or eradication of menopausal symptoms. All participants will be contributing to Medical and Homoeopathic knowledge, on the benefits and risks of alternative therapies.

The results of the study will be made available to you on request at the conclusion of the trial. If you wish to continue with the medication after the study you will be told where it can be purchased.

I, the researcher, have explained the procedures and answered any questions from the participants to the best of my ability.

A signed copy of this consent form will be made available to you, the participant.

RESEARCHER: CHARLES MUILA
CONTACT NUMBER: 0728915055
SIGNATURE: ____________________ DATE: ________________

SUPERVISOR: Dr KS PECK
CONTACT NO: 0828242280
SIGNATURE: ____________________

I have been fully notified about the procedures that will be followed in this research study. If, at any time, I have more questions about the study, I understand that they will be answered. In signing this consent form, I agree to the method of treatment and understand that I may withdraw my consent at any time.

PARTICIPANT NAME: ____________________
SIGNATURE: ____________________ DATE: ________________
APPENDIX C

PATIENT PROFILE AND CASE HISTORY

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<td>Age</td>
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<td>Marital status</td>
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<tr>
<td>Cell number</td>
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<tr>
<td>Control number</td>
<td></td>
</tr>
<tr>
<td>Date and time of Examination</td>
<td></td>
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</tbody>
</table>

Please note: only female participants between the age of 40-60 years are required for this study.

Vital signs

Temperature : _______________

Pulse rate : _______________

Blood pressure: _______________

Breathing Rate: _______________

Weight : _______________

Height : _______________

CAJ Cold

Yes No

1. Is the volunteer between 40 and 60 years of age? 

□ □
2. Which menopausal symptoms is the patient experiencing?

2.1. Hot flushes
2.2. Profuse sweating
2.3. Heart palpitation
2.4. Headache
2.5. Depressive moods
2.6. Nervousness/ irritability
2.7. Sleeping problems
2.8. Feelings of vertigo
2.9. Inability to concentrate
2.10. Joint pain

3. 3.1. Is the volunteer on any other treatment for menopause?

If the volunteer has been on hormone replacement therapy before:
3.2. Has the volunteer been off the therapy for three months or more?

4. Menstrual history:
4.1. Date of menarche: ____________________________
4.2. Dysmenorrhea: ________________________________
4.3. Length of time that menopausal symptoms have been experienced: __________________
4.4. Is the volunteer still menstruating? ____________________________
   If NO, date of the last menstrual period ____________________________

5. Medical history:
5.1. Chronic diseases: ________________________________
5.2. Operations: ________________________________
5.3. Current medications: ________________________________
5.4. Long term medications: ________________________________

6. Menopausal symptoms:
6.1. Is the cause of any of the menopausal symptoms due to a process unrelated to menopause? ____________________________
6.2. Is the menopause natural? ____________________________
7. Any aggravating events?

e.g. drinking hot drinks, drinking alcohol, getting angry or upset, excitement, seasons, coffee, tea, embarrassment or humiliation, bending over, stuffy rooms, other?
APPENDIX D

How to take Medication

1. Take 10 drops of Remedy A in a tablespoonful of water before meal in the morning or before 12pm.

2. Take 10 drops of Remedy B in a tablespoonful of water before retiring at night or before 12am.

3. Your mouth must be clean and without strong odours e.g. caffeine, nicotine, alcohol and toothpaste.

4. If you forget to take medication, mark on the calendar which medication you forgot to take and the date.

5. Do not double your dosage, because you were unable to take the previous dosage.
APPENDIX E

THE ABBREVIATED KUPPERMAN MENOPAUSE INDEX

Instructions:
The participant will complete the index at each consultation with the help of the researcher. This abbreviated Kupperman Index has been included to help the researcher and the participant in recording the progression of the trial. After the consultation, the researcher will transfer the information from the abbreviated index to the participant’s full Kupperman Menopause Index to compare results.

The participant is requested to grade the severity of her symptoms as follows:

1. Severe ...................... 3
2. Moderate .................... 2
3. Mild ......................... 1
4. Not present ................. 0

This number is recorded and then multiplied by a constant; the resultant value is also recorded. The Kupperman Menopause Index assigns a greater significance to the "more typical" menopausal symptoms by way of this higher constant value. The resulting values for each symptom are added and a total values for the Menopause Index is determined. The Menopause Index thus gives an indication of the severity of the menopausal symptoms, as experienced by each individual patient. The severity of the index is categorized as follows:

1. >35 ......................... severe
2. 20-35 ....................... moderate
3. 15-20 ....................... mild
4. <15 ......................... favourable therapeutic result

The abbreviated index therefore allows the participant to quantitatively record the way she is experiencing the typical symptoms of menopause.
The Abbreviated Kupperman Menopause Index

Participant name: ........................................
Remedy reference number: ............................

The participant is requested to grade the severity of her symptoms as follows:

1. Severe..................3  
2. Moderate..................2  
3. Mild..................1  
4. Not present..................0

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<td>Profuse sweating</td>
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<td>Sleeping problems</td>
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</tr>
<tr>
<td>Nervousness/ irritability</td>
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<tr>
<td>Depressive moods</td>
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<td>Feelings of vertigo</td>
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<tr>
<td>Inability of concentration</td>
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<tr>
<td>Joint pain</td>
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<tr>
<td>Headache</td>
<td></td>
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<td>Heart palpitation</td>
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APPENDIX F

THE KUPPERMAN MENOPAUSE INDEX

Participant Name: 
Remedy reference number: 

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<th>Second Month</th>
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(Kupperman et al, 1959)
## WILCOXON RANK SUM TEST

### Paired Samples Statistics

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