MENOPAUSAL SYNDROME

BY

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I, Siobhan Sarah Hagen declare that this dissertation represents my own work, both in conception and execution.

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ABSTRACT

The purpose of the study was to determine the effectiveness of the selected Homoeopathic remedy on the menopausal syndrome in terms of the patients perception of the treatment. It was hypothesized that the Homoeopathic medicine would improve the patients perception of the treatment.

Participants were drawn from the greater Durban area. Convenience sampling was used to draw patients into the trial. Volunteers responded to advertisements that had been placed in various advertising media. For acceptance into the trial, the participants were required to have a gynecological examination by a registered gynecologist, to confirm that they were menopausal. Of the participants meeting the above criteria thirty were chosen to participate in the trial. Fifteen constituted the placebo/control group and were given a placebo, and fifteen constituted the treatment group and were given the selected Homoeopathic medicine according to their simillimum. This was a double blind study with the medicine being dispensed on a random basis by a qualified pharmacist in order to eliminate bias. Three participants dropped out in the early stages of the study and were replaced by three other patients.

Patient perception was measured by means of questionnaires

for three months. The Psychological General Well-Being Index (PGWB) questionnaire measured psychological symptoms on a weekly basis and the Patient Perception (PPER) questionnaire measured physical symptoms on a ten daily basis, a hot flush score sheet was filled in on a daily basis.

Statistical analysis of the results using the paired T-tests revealed statistical differences for the Psychological General Well-Being Index between the initial and final symptom scores of the treatment group. The components of the questionnaire that showed improvement were anxiety ($p = 0.017$), depression ($p = 0.018$), well-being ($p=0.001$), health ($p=0.032$), vitality ($p=0.003$). The treatment group showed an improvement of 86.7%, 13.3% worsened. The placebo group showed no statistical difference between the initial and final symptom scores. The placebo group showed an improvement of 53.3%, 46.6% worsened.

Statistical analysis of the results of The Patient Perception questionnaire, using the paired T-test, showed a significant difference between the initial and final symptom scores for the treatment group for vasomotor symptoms ($p = 0.001$), emotional symptoms ($p = 0.001$), and other symptoms ($p=0.000$). The treatment group showed an improvement of 100%. The placebo group showed a

statistical difference for the vasomotor symptoms (p = 0.019), the other symptoms showed no statistical difference. The placebo group improved by 60%, and 40% worsened.

The hot flush score sheet showed a 53.3% improvement in hot flush occurrence for the placebo group, and a 86.7% improvement for the treatment group. Both groups showed 6.7% that did not change, 40% of the placebo group worsened, and 6.7% of the treatment group worsened.

The un-paired T-tests revealed, with a significance level of 95%, that the treatment and placebo groups were not statistically different, for the Psychological General Well-Being Index and Patient Perception questionnaires.

In concluding it would seem that experimentally the Homoeopathic remedies caused an improvement in the patients perception of the treatment. Overall the PGWB treatment group showed a 33% greater improvement than the placebo group (Table 4.1.2 and 4.1.4). The PPER treatment group showed a 40% greater improvement over the placebo group (Table 4.1.8 and 4.1.12). However, the treatment and placebo groups did not show a significant statistical change between themselves. It can therefore not be concluded that the Homoeopathic medicines alone caused an improvement in the patients perception of the treatment.

UITTREKSEL

Die doel van die studie was om die effektiwiteit van die geselekteerde Homoeopatiese geneesmiddel op die menopousale sindroom te bepaal, in terme van die patient se persepsie van die behandeling. Daar is veronderstel dat die Homoeopatiese medisyne die patient se persepsie van die behandeling sou verbeter.

Deelnemers aan die studie, is getrek vanuit die groter Durban area. Gemaklikheidstoetsing is gebruik om patiente by die proefneming te betrek. Vrywilligers het gerageer op advertensies wat in verskeie advertensie-media geplaas is. Om tot die proefneming toegelaat te word is daar van deelnemers verwag om 'n ginekologiese ondersoek deur 'n geregistreede gineloog te ondergaan, om te bevestig dat hulle wel menopousal is. Van die deelnemers wat aan die bogenoemde kriterium voldoen het, is dertig gekies om die proefneming deel te neem. Vyftien deelnemers het die placebo\kontrole-group uitgemaak en 'n troosmiddel is aan hulle gegee. Die ander vyftien persone het die behandelingsgroup uitgemaak. Aan hulle is geselekteerde Homoeopatiese middels volgens elkeen se simillium gegee. Hierdie was 'n dubbele blinde studie deurdat die medisyne op 'n lurake basis uitgegee is deur 'n gekwalifiseerde apteker, om sodoende bevooroordeling uit te skakel. Drie deelnemers het in die beginstadiums van die toetsing

uitgeval en is vervang deur drie ander pasiente.

Patient-persepsie is vir drie maande gemeet deur middel van vraelyste. Die Psychological General Well-being (PGWB) vraelys het op 'n weeklikse basis die psigologiese simptome van die pasient gemeet. Die Patient Perception (PPER) vraelys het fisiese simptome op tien-daagikse basis gemeet, terwyl 'n lys van warm gloede op 'n daaglikse basis ingevul is.

Statistiese analise van die resultate waar gepaarde T-toetsing gebruik is, het statistiese verskille vir die PGWB vraelys tussen die aanvanklike en finale simptome-tellings van die behandelingsgroup aan die lig gebring. Die komponente van die vraelys wat verbetering getoon het is: angs ($p=0.017$), depressie ($p=0.018$), welsyn ($p=0.01$), gesondheid ($p=0.032$), lewenskragtigheid ($p=0.03$). Die behandelingsgroup het 'n verbetering van 86.7% getoon, terwyl 13.3% van die groep verswak het. Die placebo-groep het geen statiestiese verskil getoon tussen die aanvanklike en finale simptome-tellings nie. Die placebo-groep het 'n verbetering van 53.35 getoon, terwyl 46.6% van hierdie group verswak het.

Statistiese analise van die resultate van die PPER vraelys, waar gebruik gemaak is van die gepaarde T-

toetsing, het 'n merkbare verskil getoon tussen die aanvanklike en finale simptome-tellings van die behandeingsgroup: vasomotoriese simptome (p=0.001), emosionele simptome (p=0.001), ander simptome (p=0.000). Die behandelingsgroup het 'n 100% verbetering getoon. Die placebo-group het 'n statistiese verskil getoon ten opsigte van vasomotoriese simptome (p=0.019), terwyl die ander simptome geen verskil getoon het nie. Die placebo-groep het 60% verbeter terwyl 40% van hierdie group verswak het.

Die warm gloede tellingskaart het 'n verbetering van 53.3% ten opsigte van die voorkoms van warm gloede getoon by die placebo-groep, terwyl 'n verbetering van 86.7% verkry is deur die behandelingsgroup. Beide groupe het 'n waarde van 6.7% getoon ten opsigte vanonveranderde simptome. Veertig persent van die placebo-groep het versleg teenoor 'n verslegting van slegs 6.6% by die behandelinsgroep.

Die ongepaarde T-toetsing het, met 'n beduidenswaardige vlak van 95% gewys dat die behandelinsgroep en die placebo-groep nie statisties verskillend was ten opsigte van die Psycholgical General Well-Being en Patient Perception vraelyste nie.

Ter afsluiting wil dit oorkom dat Homoeopatiesemiddels

eksperimenteel 'n verbetering in patiente se persepsie van behandeling teweeg gebring het. Totaal het die PGWB behandelingsgroep 'n groter verbetering van 33% oor die placebo-groep getoon (tabel 4.1.2. en tabel 4.1.4). Die PPER behandelinsgroep het 'n groter verbetering van 40% oor die placebo-groep getoon (tabel 4.1.8 en tabel 4.1.12). Nogtans die behandelinsgroep en placebo-groep het egter nie statisties beduidend verskil ten opsigte van mekaar nie. Die afleiding kan dus nie gemmak word dat die Homoeopatiese medisynes alleenlik 'n verbetering in patient persepsie ten opsigte van behandeling teweeg gebring het nie.

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PGWB: Psychological general well-being index questionnaire.

PPER: Patient Perception questionnaire.

LH: Luteinizing hormone.

FSH: Follicle stimulating hormone.

INTRODUCTION

According to the World Health Organization, the global life expectancy at birth was 55 years in 1974, will be 63 years in 2000, and will be close to 70 years in the year 2025. By the year 2025, approximately 20% of the world's population will be more than 60 years old. The problems associated with hormonal changes become significant when more than one third of a woman's life will be concentrated in the menopausal years (Crosignani 1992).

Menopause represents a major cultural, psychological and physiological milestone in a woman's life. It may therefore seem logical to refrain from intervening in a natural process. However, the female menopause is a period of intense hormonal adjustment which can be accompanied by considerable discomfort (Anon 1986). The menopause can result in a number of distressing short and long term symptoms and the complaints often are so severe that they become a syndrome which requires specific therapy (Roberts 1992). In a survey conducted to obtain insight into the general practioner's view regarding climacteric, 95% were of the opinion that women with climacteric complaints need some kind of medical help, and 62% were found to prescribe medication (Stouthamer ET AL. 1993). If treated, many symptoms and complications can be avoided.

Conventional therapy for menopause involves hormone substitution, prescription of sedatives and tranquilizers. This constitutes replacement therapy which may correct the superficial deficiency, but does not correct the underlying imbalance. This leads to dependence of general emotional and physical health on substances which such therapy entails (ANON 1986). These therapies are costly and may have undesired side effects resulting in many women's fear of conventional treatment of menopausal. Women on hormone replacement therapy (HRT) may experience symptoms such as fluid retention, breast tenderness, weight gain, nausea, headaches and premenstrual syndrome type symptoms. Harmful side effects of HRT may be the increased risk of breast cancer and endometrial cancer (Wilson 1992). It is the purpose of this investigation to evaluate the effectiveness of homoeopathic remedies on the menopausal syndrome. If the homoeopathic remedies are found to be effective it will offer several advantages over conventional HRT. These include elimination of the side effects, and lower costs.

CHAPTER ONE

1.1 THE STATEMENT OF THE SUBPROBLEM

The purpose of this investigation is to evaluate selected homoeopathic remedies for the menopausal syndrome, in terms of patients perception of the treatment, in order to evaluate the effectiveness of the selected remedy on the menopausal syndrome.

1.2 SUBPROBLEMS

1.2.1. The First Subproblem

The first subproblem is to evaluate selected homoeopathic remedies for the menopausal syndrome, in terms of the patients perception of the treatment, with the use of questionnaires in order to determine the effectiveness of the remedy on the menopausal syndrome.

1.2.2. The Second Subproblem

The second subproblem is to analyze and interpret the collected data in order to determine the effectiveness of the remedy on the menopausal syndrome.

1.3. HYPOTHESIS

1.3.1. Hypothesis One

The first hypothesis is that the remedy will result in the patient having a positive perception of the treatment, that is, an improvement of their symptoms.

1.3.2. Hypothesis Two

The second hypothesis is that the integration of the results will show that the homoeopathic remedy is effective in the treatment of the menopausal syndrome.

1.4. DELIMITATIONS

1- Women will be admitted only under the condition that they have not received hormone replacement therapy and that they have not had a hysterectomy or an oophorectomy.

2- This study will not attempt to explain the mechanism of action of the homoeopathic medicine.

1.5. ASSUMPTIONS

1- It is assumed

a) that the pathogenesis for the remedies are accurate.

b) that the patients will take the medicine as prescribed.

c) that the medicine will be prepared as set out in the homoeopathic pharmacopoeia.

DEFINITIONS

CLIMACTERIC

The phase in the ageing of woman marking the transition from the reproductive phase to the non-reproductive state.

MENOPAUSE

The final menstrual period, or cessation of menses defined after twelve consecutive months of ammenorhoea.

MENOPAUSAL SYNDROME

The climacteric is associated with symptomatology and can be viewed as a syndrome.

HORMONE

A chemical substance, produced by an endocrine gland, which has a specific regulatory effect on the activity of a certain organ or organs.

OESTROGEN

A generic term for estrus-producing steroid compounds; the female sex hormone.

OESTRADIOL

The most potent naturally occurring ovarian and placental oestrogen in humans.

OESTRONE

An oxidation product of estradiol, less potent than estradiol, also secreted by the ovary. Circulating estrone is for the most part derived from estradiol.

CORPUS LUTEUM

A yellow glandular mass in the ovary formed by an ovarian follicle that has matured and discharged its ovum.

PROGESTERONE

Hormone liberated by the Corpus Luteum adrenal cortex and placenta. Its function is to prepare the uterus for reception and development of the fertilized ovum by transformation of the endometrium from the proliferative to the secretory stage.

HOMOEOPATHY

Therapeutic method based on administering a substance capable of provoking, in the healthy individual, disorders analogous to those found in the sick person. In this respect one administers, minute or infinitesimal doses.

FOLLICLE STIMULATING HORMONE

Hormone that is secreted by the anterior lobe of the pituitary gland. Its action stimulates the development of the ovarian follicle to produce and secrete oestrogens.

LUTEINIZING HORMONE

Hormone secreted by the anterior lobe of the pituitary gland. Serves to stimulate ovulation and progesterone secretion by corpus luteum.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 INTRODUCTION

Investigation postulates the uniformity of nature: in medicine this means that a particular treatment applied in a particular situation will always have the same effect, provided the treatment and the situation are the same, in all relevant respects. In controlled experiments of treatments which operate by molecular pharmacology, these conditions are met when patients of identical clinico-pathological diagnosis are selected (Owen 1983).

The adequate performance of the healthy organism is ensured by many physiological auto-regulatory systems. During our lives, we are constantly under different aggressions that we handle without even being aware of them. If these aggressions become too intense, regarding our reactional possibilities, our auto-regulation systems are overwhelmed, and we display suffering symptoms. We then present abnormal reactions which can affect different levels and translate themselves in objective and subjective symptoms. However individuals react differently to similar aggressions. That is, that each individual has a different terrain, determining for each his own way of reacting to an aggression. This terrain

notion dominates the therapeutics in chronic pathology. It is well known and recognized by all clinicians, who observe daily, that individuals manage disease differently. Each problem that the patient presents with must be looked at in the context of the individual.

Homoeopaths know that symptoms are merely the bodies best attempt at demonstrating and correcting an imbalance. Unless the illness is worked with on the plane from which it originates and not just suppressed with drugs, a deeper more severe illness may result. Drugs act by separating us from the working of our body and often act to dull our consciousness. The danger being that we are unaware of the disease and the illness then progresses without our body knowing it. The homoeopathic remedy, correctly applied, roots out the cause and corrects the imbalance (Stoff 1983).

2.2 HOMOEOPATHIC TREATMENT OF MENOPAUSE

Each problem that the patient presents must be looked at in the context of the individual. Each patient taking part in the study will have an extensive case history taken and will then receive a remedy according to their similimum.

The application of these remedies is not a case of substitution therapy, but rather biological stimulation

without hormones of the ovaries and connected glandular system, such as the pituitary and the suprarenal glands, in the sense of harmonizing functional regulation.
In view of the fact that the effect is not directed one-sidedly onto a member of the entire menopausal syndrome, but acts on the entire individual, other, apparently secondary conditions, will also be improved (Riley 1992).

2.3. MENOPAUSAL STATES

In Western countries women now live an average of 75-80 years. Mortality from childbirth is negligible and death rates before the age of fifty are low. The implication is that the menopaused woman can expect to live approximately thirty years after that event (Mc Kinley ET AL. 1992). Population studies suggest that there will be a significant increase in the size of the postmenopausal population over the next two decades. This will inevitably lead to greater demands on the health care resources.

Two menopausal states can be defined:

1 - The first state is natural menopause or the natural cessation of menses defined after twelve consecutive months of amenorrhoea.

2 - The second state is surgical menopause which is the cessation of menses due to the removal of the uterus.

This study will deal with women undergoing natural

menopause.

Natural menopause involves three phases:

1 - Firstly, women who have had menstruation within the prior three months with no changes in the regularity of the cycle, or a change that was represented at only isolated interviews, are pre-menopausal.

2 - Secondly, women who report three to eleven months of amenorrhoea at one contact and increased menstrual

irregularity at the next, are menopausal.

3 - Thirdly, women reporting permanent amenorrhoea are post-menopausal (Mc Kinley ET AL. 1992).

These three phases are collectively called the climacteric (Wilson 1992).

2.4 SYMPTOMS

Due to intense hormonal adjustment women may experience a variety of bothersome symptoms at the climacteric (Stouthamer ET AL. 1993). These can be divided into three categories:

1 - Menopause specific

2 - Physical

3 - Psychological

Altogether make up the menopausal syndrome.

The physical symptoms are headaches, palpitations, joint

pains, backaches, shortness of breath and painful intercourse.

The psychological symptoms include vertigo, depression, insomnia, lack of energy, loss of appetite, irritability, nervousness, decreased concentration and decreased libido.

The menopause specific symptoms are hot flushes, outbreaks of sweating, menstrual irregularity and vaginal dryness (Mc Kinley ET AL. 1992).

When an individual patient presents with a number of climacteric complaints, it is not easy to distinguish whether they are caused by endocrine changes, chronological ageing, social or psychological factors or interactions between these factors (Holte and Mikkelson 1991). Endocrinology factors contribute to variance in only a few of complaints, that is, hot flushes, sweating, menstrual irregularity and vaginal dryness.

2.4.1 MENOPAUSE SPECIFIC SYMPTOMS

HOT FLUSHES

The hot flush is recognised by the medical profession and lay public as the most characteristic manifestation of the climacteric. Hot flushes may be experienced several times per day, once a week or less frequently. They may be a

slight annoyance or severely debilitating. The more intense flushing involves sweating. If these occur at night there is a resultant "domino effect" causing insomnia, irritability and general lethargy (Brincat ET AL. 1984). According to a report in the Journal of American Geriatrics (Sept. 1982), they usually cease within one to five years, but some report them over ten years. Many report hot flushes long after menstruation has stopped. Typical complaints include: sudden perspiration, feeling chilly, clammy or breaking out in a cold sweat, waking up at night drenched with sweat, feeling embarrassed at flushing, shivery with no control. Prodromal symptoms are common and for many include a feeling of increasing pressure in the head, though most women have difficulty describing the sensation. For most hot flushes start in the face, neck, head, chest and the initial focal point may be specific such as an earlobe , forehead or between the breasts (Brincat ET AL. 1984).

The pathogenesis of cold sweat is uncertain. The etiology is complex and many possible factors have been implicated including the hypothalamus, pituitary, gonadotropins and neurohumeral pathways. The association between plasma calcitonin and beta endorphin has been shown in various studies with thermoregulatory effects. An increase in plasma calcitonin levels was noted during the hot flushes, and a decrease of beta endorphin levels was noted at the

onset of the hot flush (Tepper ET AL. 1992). A hormonal etiology seems likely in view of the association of the flushing with the climacteric and the well proven clinical value of oestrgen therapy in eliminating hot flushes (Brincat ET AL. 1984). There is a close relationship between the onset of hot flushes and luteinizing hormone secretion. Luteinizing hormone increases with menopause and sets up flushes by dilating surface blood vessels. Alteration of catecholamines, prostaglandins, endorphins or neurotensin in conjunction with low oestrogen production may also play a role. The precise role that oestrogens play has yet to be established (Harrison 1991).

The hot flushes may also be due to nerve activity in the hypothalamus which controls temperature and the pituitary gland which releases luteinizing hormone. Women who have sudden cessation of ovarian function have severe hot flushes and some with off again, on again ovarian function go through years of hot flushes (Kahn and Holte 1989). The rate of hot flushes reporting is related to the duration of the perimenopause. Women with longer perimenopause were more likely to report hot flushes. Women who reported having pre-menstrual tension before the menopause were more likely to experience vaso-motor symptoms when they become peri-menopausal. Women who reported having pre-menstrual tension may have developed certain reactions

to menstrual processes, thus anticipating symptoms when there were changes in their menstrual pattern or there may be some sort of hormonal vulnerability in these women (Mc Kinley ET AL. 1992).

GENITAL CHANGES

The vagina, uterus and cervix are areas where oestrogen is readily taken up, and which consequently suffer when deficiency occurs (Wilson 1992). Decreased oestrogen causes vaginal dryness, vaginal atrophy and decreased elasticity. Decreased blood supply leads to fragility of the tissues and increased susceptibility to infections and results in painful intercourse (Kahn and Holte 1989). Shrinkage of the uterus and cervix, together with shortening of the cervical canal, also occurs (Wilson 1992). Menstrual irregularity may be due to decreased progesterone causing an oestrogen imbalance and resulting in heavy and erratic menses. Some obese women have high oestrogen levels and therefore have heavier periods, whilst thin women have usually less oestrogen and therefore lighter periods (Kahn and Holte 1989). The irregular and heavy menstrual bleeding interspersed with periods of amenorrhoea may be worrying, especially if they last beyond two years.

2.4.2 PHYSICAL CHANGES

Hormones in the body cause other changes in menopause,

that is, increased facial hair due to increased androgens, decreased size of the breasts due to decreased oestrogens, decreased elasticity and tone of the skin due to decreased oestrogen and also thinning of the hair (Mc Kinley ET AL. 1992).

SEXUAL SIGNS

Sexual difficulties are common during the menopause and may include poor sexual response, discomfort during intercourse, decreased libido and loss of interest in the sexual partner (Wilson 1992).

CARDIOVASCULAR CHANGES

The risk for cardiovascular disease is greater for those who have reached premature menopause. Extensive studies have shown the protective factor that ovarian sex hormones give against coronary heart disease (Wilson 1992).

HEADACHES

Changes in oestrogen levels during menopause may trigger or change the prevalence of migraines. Estrogen produces changes in prostaglandins, hypothalmic opoids, and prolactin secretion, which may in part account for the genesis of the headache (Silberstein 1992). In women who have undergone surgical ovariectomy, the natural course of migraine is worse than those who have a physiological menopause (Neri ET AL. 1993).

2.4.3 PSYCHOLOGICAL SYMPTOMS

Menopausal complaints often arise from psychological factors and most menopause research has been based on cross sectional studies. A consistent finding has been that much of the variance in symptoms and complaints reported by women during the climacteric can in fact be accounted for by a number of different adverse psychological and socio-demographic factors (Downes 1992). It is postulated that the mechanism whereby these factors exercise their effect can be conceptualized in the form of a vulnerability model. The vulnerability model has emerged from cross-sectional studies and it implies that the presence of adverse socio-demographic factors renders women vulnerable at the time of menopause to develop physical and psychological symptoms.

A - SOCIO-DEMOGRAPHIC FACTORS:

Mainly underprivileged women of low socio-demographic status, low income, low educational level and with limited employment opportunities, suffer most during menopause.

B _ PSYCHOLOGICAL FACTORS

Negative attitudes to menopause, poor social support, poor marital relations, stressful life events and recent bereavements, have all been found to be

associated with symptoms (Green 1992).

The model implies the actual symptoms women experience, and their severity, are determined by the woman's biological and psychological make-up, her past experiences, and the way she has reacted to adversity in the past. Hence the widespread variation in the nature and severity of the symptoms. Although these women respond to the menopause transition by exhibiting "illness" in the form of symptoms, there is no typical menopause picture as regards to these symptoms. Some women may exhibit a predominantly psychological profile, others a somatic and others a mixture (Green 1992).

Wide variation in women's responses to menopause, may be explained by the identity continuity theory. It briefly states that women who have found satisfaction in their principle life role, continue to identify with that role. Individuals who have not considered themselves successful in their principle life role, attempt to maintain a tenuous role identity by continuing to perform various tasks. Thus, even in societies in which women's roles are more active and continuous throughout their lives, women who have not been satisfied at the onset of menopause are less likely to experience well-being during the climacteric years (Smyke 1991).

For the majority of women menopause is not associated with

psychological symptoms. Approximately 30% of women report psychological symptoms. These symptoms are often associated with past emotional problems, social problems and occurrence of recent life stresses (Greene and Cooke 1980).

2.5 FACTORS AFFECTING MENOPAUSE

Factors associated with the menopause are poorly understood (Torgerson ET AL. 1994). Several factors affect aspects of menopause i.e. age, education, parity, body mass and smoking (Mc Kinley ET AL. 1992).

Vague somatic complaints increase with the age difference between spouses (husbands older) and where the subject reported that her mother had psychological complaints at the menopause. Nervous complaints occur more in the midlife if the subject reported that her mother had had psychological complaints at the same time.

It is also well established that cigarette smokers reach the menopause approximately two years earlier than the non-smokers and the amount of smoking was associated with vaso-motor and nervous complaints. Results show the immediate toxic impact of the by-products of smoking on ovarian function (Holte and Mikkelson 1991). Cigarettes may be antioestrogenic, disturb hypothalmic function and inhibit the enzymes aromatase and desmolase which are

involved in oestrogen synthesis. In addition female smokers have a more androgenic profile (Torgerson ET AL. 1994) .

Slender women usually experience menopause earlier than obese ones and athletic women before sedentary ones. High meat and fat diet may also prolong menses (Kahn and Holte 1989). There is a direct influence of meat per se on hormonal function. Vegetarianism leads to decreases in the episodic releases as luteinizing hormone (LH), follicle stimulating hormone (FSH) and the length of the menstrual cycle, whilst, conversely, the inclusion of meat protein increases the episodic releases of LH, FSH and the length of the menstrual cycle. It is possible that high fibre intakes may interrupt the enterohepatic circulation of sex hormones thus leading to lower oestrogen levels in vegetarians.

There is a relationship between older menopausal age and increasing alcohol consumption. There is evidence that alcohol may be oestrogenic at moderate levels of consumption (Torgerson 1994).

Considerable social psychological research has demonstrated that a woman's behavior can be affected by her expectations and can be regarded as a self-fulfilling prophecy. Poor expectations and attitudes towards menopause can influence subsequent symptom reporting.

Negative attitudes towards menopause result in depression and higher symptom reporting (Avis and Mc Kinley 1991). Being under stress before menopause, having hypochondriac concerns and not taking regular exercise were associated with depression.

Sleep problems, having difficulty getting off to sleep, early a.m. waking were reported more frequently by women who had suffered ill health and who had difficulty coping with symptoms before menopause were also depressed during menopause. Depressed women might anticipate the menopause more negatively and feel more hopeless about it than those not depressed (Hunter 1992). These findings suggest the menopausal syndrome may be more related to personal attitudes than to menopause per se.

Women generally reach menopause when their children are leaving home and they face an "empty nest". At the same time, they loose their status and prestige that Western culture reserves for their young. The depression associated with menopause is now commonly called the "empty nest syndrome". This term refers to difficulties women encounter when their children leave home or go to college, gain employment or get married. Women who are no longer needed by their children, may stagnate and become pathologically self absorbed. Employment away from the home is very important as it is an opportunity to redirect

energies gradually as material responsibilities lessen. Employed women fare much better in menopause than unemployed women (Smyke 1991).

Ten percent of women do not experience the menopausal syndrome, their menses just stop (Kahn and Holte 1989). Diseases may also influence menopause and patients will undergo a gynecological examination to exclude patients with disorders of the uterus, pelvic inflammatory disease, and diseases of the ovaries, breast and urinary tract. Diseases associated with early menopause are "vulvar dystrophy" and osteoporosis. Diseases associated with late menopause include diabetes, cancer of the uterus, breast and cervix as well as fibroids and polyps (Kahn and Holte 1989).

2.6 THE ROLE OF THE ENDOCRINE SYSTEM

An understanding of the endocrine system, and the critical role it plays in establishing and maintaining a woman's hormonal balance, is essential in approaching menopausal disorders. Restoring a state of balance is one of the keys to successfully treating the menopausal syndrome. The four primary hormones responsible for the endocrine balance in women are luteinizing hormone , follicle stimulating hormone oestrogen and progesterone. These hormones control the female menstrual cycle, and are susceptible to many influences such as stress, nutrition,

physical exercise and endocrine problems (Riley 1992).

During their 40's and 50's certain universal physical events occur in women: their oestrogen levels decrease, ovulation stops and production of luteinizing and follicle stimulating hormone increases. The most active hormones are oestrogen and progesterone. Oestrogen is the name of a category of hormones having common effects. The ovaries produce oestrogen as well as the skin, adrenals and fatty tissue. They stimulate the uterus lining to prepare for ovulation, influence the depth and thickness of the vaginal walls, stimulate breast development and also affect the skin hair, blood, liver and bones. Premenopausal oestrogens are in the form oestrone. Progesterone is produced by the ovaries. It changes the lining of the uterus and prepares the body for pregnancy. A decrease in progesterone during menopause leads to erratic and heavy menses (Kahn and Holte 1989). In cultures whose diets are rich in fresh vegetables of all sorts, progesterone deficiency does not exist. Worldwide the most common source of progesterone is the wild yam. Diets high in yam consumption provides sufficient progesterone to prevent menopausal problems that doctors see every day (Lee 1989).

2.7 HORMONE REPLACEMENT THERAPY

Replacement therapy is the mainstay of allopathic medicine

and may correct the superficial deficiency, but is not directed at correcting their underlying endocrine imbalance. The conventional allopathic treatment is oestrogen and progesterone (Riley 1992). The replacement therapy decreases hot flushes, decreases vaginal dryness and may or may not reduce emotional mood swings and depression. The hormone replacement therapy has numerous side effects: Recurrence or monthly bleeding for an extended time, fluid retention and weight gain, worsening asthma and migraines, breast tenderness, abdominal cramps, nausea and vomiting irritability, fibroid tumors of the uterus, endometrial and uterine cancer, high blood pressure, increased incidence of strokes, gall-bladder and liver disease (Kahn and Holte 1989).

It is therefore understandable, that women's attitudes towards these orthodox treatment possibilities, are ambivalent. Women are suspicious of the dependence of their general emotional and psychical health on the substance which the therapy entails. Widely prevailing fear of iatrogenic damage, and of the undesired side effects of hormone administration, certainly play a major role in misgivings of many women. Biological homoeopathic remedies are therefore finding increasing acceptance in this area. These are consequently more frequently administered by Homoeopaths. It is the purpose of this investigation to see if homoeopathic remedies are

effective.

2.8 SUMMARY

To summarize, menopausal complaints results from:

Firstly, decreased ovarian activity with subsequent hormonal deficiency causing symptoms of hot flushes, menstrual irregularities and atrophic vaginitis and other symptoms in various organs.

Secondly, sociocultural factors determined by the women's environment.

Thirdly, psychological factors resulting from the individual woman's character.

The variety of symptomalogy results from an interaction of these three components. The study of the menopausal syndrome will identify these factors by the use of questionnaires and comprehensive case histories. The patient will be treated as an individual, and a homoeopathic remedy specific to each patient will be given. The remedies effectiveness will be monitored by means of questionnaires. Factors affecting patient compliance and participation need to be considered.

Patients may not complete the study and this will be taken into account.

CHAPTER THREE

3 THE DATA

The data of this research is of two kinds: primary data and secondary data. The nature of these two types of data will be given briefly below.

3.1 The primary data

Four types of primary data are needed:

1. The responses of the patients to the questionnaire on perception of the treatment.
2. Results of the gynecological examination will determine if patients may participate in the study.
3. The integration of the results of the patients perception of the treatment and the response of the patients symptoms to the medication given.

3.2 The secondary data

Journals and books on menopause and hormones are needed.

3.3 The criteria governing the admissibility of the data.

Only the data from the questionnaires completed by the menopausal patients undergoing treatment will be used. Only patients who have previously been diagnosed by a selected gynecologist as being acceptable for the study

will be treated.

3.4 THE RESEARCH METHODOLOGY

The purpose of this investigation is to evaluate selected homoeopathic remedies for the menopausal syndrome , in terms of the patients perception of the treatment, in order to evaluate the effectiveness of the selected remedy on the menopausal syndrome.

A brief summary of the methodology :

1. Advertise for patients with the menopausal syndrome.
2. Select a sample group of thirty patients according to criteria defined in point 4 below.
3. The sample group will only be used under the conditions that the individuals have not received hormone replacement therapy and that they have not had a hysterectomy or an oophorectomy.
4. A chosen gynecologist will conduct a gynecological examination to exclude any patients with serious conditions.
5. Perform a case history and physical exam examination.
6. Repertorize each case to prescribe the simillimum.
7. Homoeopathic prescriptions to be made up by an appointed homoeopathic pharmacist.
8. The pharmacist randomly divides the sample in half, so

that fifteen patients receive homoeopathic medicine and fifteen patients receive placebo. One group to function as the control, and the other as a treatment group. The control group will have no knowledge that they are receiving placebo. The researcher will have no knowledge of which patients are receiving real or placebo medication, and this will serve as a double blind study.

9. A range of standardized questionnaires will be given to the patients for three months.

   1. The Psychological General Well-Being Index (reproduced with permission from Dr Wiklund) comprises 22 questions which cover the subscales of anxiety, depression, well-being, self control, health and vitality. The patients rate each question on a six-point scale (with six the most positive option and one as the most negative.) The Psychological General Well-Being Index will be filled in on a weekly basis.

   2. A questionnaire on patient perception will be filled in on a ten day basis. The patients rate 19 symptoms using visual analogue scales. The patients rate each symptom according to a grade:

      0 = No symptom

      3 = Slight symptom

6 = Moderate symptom

9 = Severe symptom

Factor analysis distinguished three factors:

A. Vasomotor symptoms (hot flushes, sweating)

B. Emotions (insomnia, nervousness, depression, irritability, decreased concentration, headache).

C. Other symptoms (palpitations, vaginal dryness, joint pain, backache, shortness of breath, painful intercourse, vertigo, loss of appetite, lack of energy, decreased libido, menstrual irregularity).

Similar symptom clusters have been used elsewhere in research. The method of self rating menopausal symptoms has been previously shown to be a sensitive and clinically valid measure of emotional and symptomatic changes in menopausal women (WIKLUND 1992).

3. A score sheet will be given to each patient where the number of hot flushes will be recorded daily.

The questionnaires allow the patient to be monitored on a frequent basis and at minimal cost. The combination of selected standardized measures, ranging from general to specific, provides relevant information, in assessing the impact of the climacteric complaints, in menopausal women, before and after treatment.

10. Patient interviews will take place on a monthly basis

and new symptoms not recorded on the questionnaire will be noted. The medication will be renewed or changed.

11. The data from the questionnaires will be statistically analyzed and interpreted.

3.5 THE SPECIAL TREATMENT OF EACH SUBPROBLEM

3.5.1 The first subproblem

The first subproblem is to evaluate selected homoeopathic remedies, for the menopausal syndrome in terms of patients perception of the treatment with the use of questionnaires, in order to determine the effectiveness of the remedy on the menopausal syndrome.

4.5.2 The data needed

The data needed for testing the hypothesis for subproblem one will be obtained from the answers to the questionnaires by the menopausal patients. The following data is needed:

a) Physical Symptoms

Headaches, palpitations, joint pain, backache, painful intercourse and urinary frequency.

b) Psychological symptoms

Vertigo, depression, insomnia, lack of energy, loss of appetite, irritability, decreased concentration and

decreased libido.

c) Menopause specific

Hot flushes, outbreaks of sweating and menstrual irregularities.

4.5.3 The means of obtaining the data.

All the data will be collected by means of questionnaires. The questionnaires will be given to those who have been accepted for the study, and they will be asked to fill in the questionnaires on a daily basis for the hot flushes, on a weekly basis for the psychological general well-being index, and on a ten day basis for the questionnaire on patient perception. At the first consultation patients will be introduced to the study, and the questionnaire will be explained.

3.5.4 The Second Subproblem

The second subproblem is to analyze and interpret the collected data in order to determine the effectiveness of the remedy on the menopausal syndrome.

3.5.2 The data needed.

The data needed to test the hypothesis of subproblem two will be the information gathered from the questionnaires to the patients in the experimental and control groups.

3.5.6 The means of obtaining the data.

The data obtained from the questionnaires will be used.

CHAPTER FOUR

Parametric testing (n=30) was used incorporating the paired and un-paired T-tests. The p values were then used to assess the degree of dissimilarity between the measurements. When the p value is between 0.05 and 0.01, the result is called statistically different; when it is less than 0.01, the result is termed highly statistically differnt (BAILER 1992).

The paired T-test was used to compare the initial questionnaire scores (month 1) with the final questionnaire scores (month 3), for both the treatment and placebo groups for the Psychological General Well-Being Index(PGWB) and the Patient Perception (PPER) questionnaires. The PGWB questionnaire was rated on a six point scale, with six as the as the most positive option and one as the most negative. The higher the number of points per PGWB questionnaire, the more positive the result.The PPER questionnaire was measured on a visual analogue scale with a rating of 0-10 points with 0 as no symptom, and 10 as severe symptom. The lower the number of points per PPER questionnaire the more positive the results.

The un-paired T-test was used to compare the patient perception of the treatment of the placebo group against that of the treament group, for the PGWB and PPER questionnaires. All the questionnaire totals used are in Appendix B.

4.1 HYPOTHESIS TESTING FOR SUBPROBLEM ONE

The paired T-test was used to compare the questionnaire score for the first and last months.

Table 4.1.1

Psychological General Well-Being Index questionnaire scores before and after placebo treatment. Placebo group.

Placebo group	Month 1	Month 3
1	74	94
2	105	114
3	105	108
4	78	73
5	107	91
6	76	58
7	112	97
8	96	111
9	99	62
10	74	94
11	99	102
12	97	94
13	91	106
14	101	98
15	88	109

Figure 4.1.1

Graph derived from values in Table 4.1.1 demonstrating any change in the patients perception to the treatment for each member of the placebo group for the PGWB questionnaire.

Figure 4.1.1

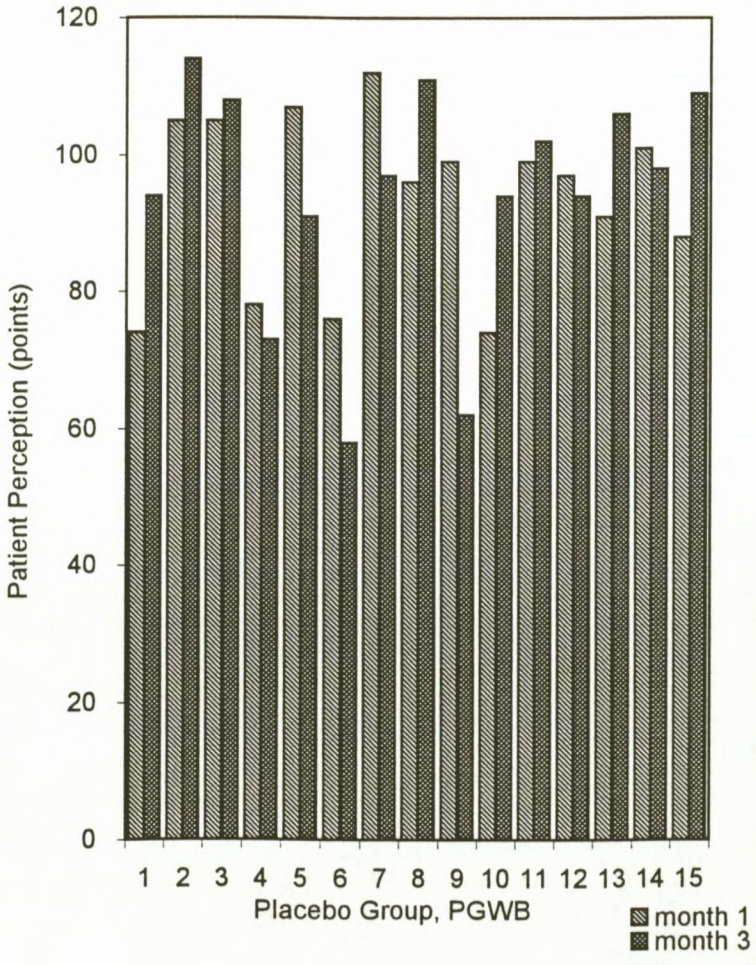


Table 4.1.2

Frequency table displaying rates of occurence for the Psychological Well-Being Index questionnaire placebo group.

Group	Improved	No change	Worsened	Total
Placebo	8 (53.33	0 (0.00%)	7 (46.67%)	15 (100.00%)

Table 4.1.3

Psychological General Well-Being Index questionnaire scores before and after homoeopathic treatment. Treatment group.

Treatmen group	Month 1	Month 3
16	125	130
17	56	74
18	83	102
19	64	112
20	117	113
21	85	103
22	37	46
23	79	98
24	110	115
25	109	125
26	91	82
27	110	126
28	72	119
29	97	106
30	87	104

Figure 4.1.2

Graph derived from values in Table 4.1.3 demonstrating any change in the patients' perception to the treatment for each member of the treatment group for the PGWB questionnaire.

Figure 4.1.2

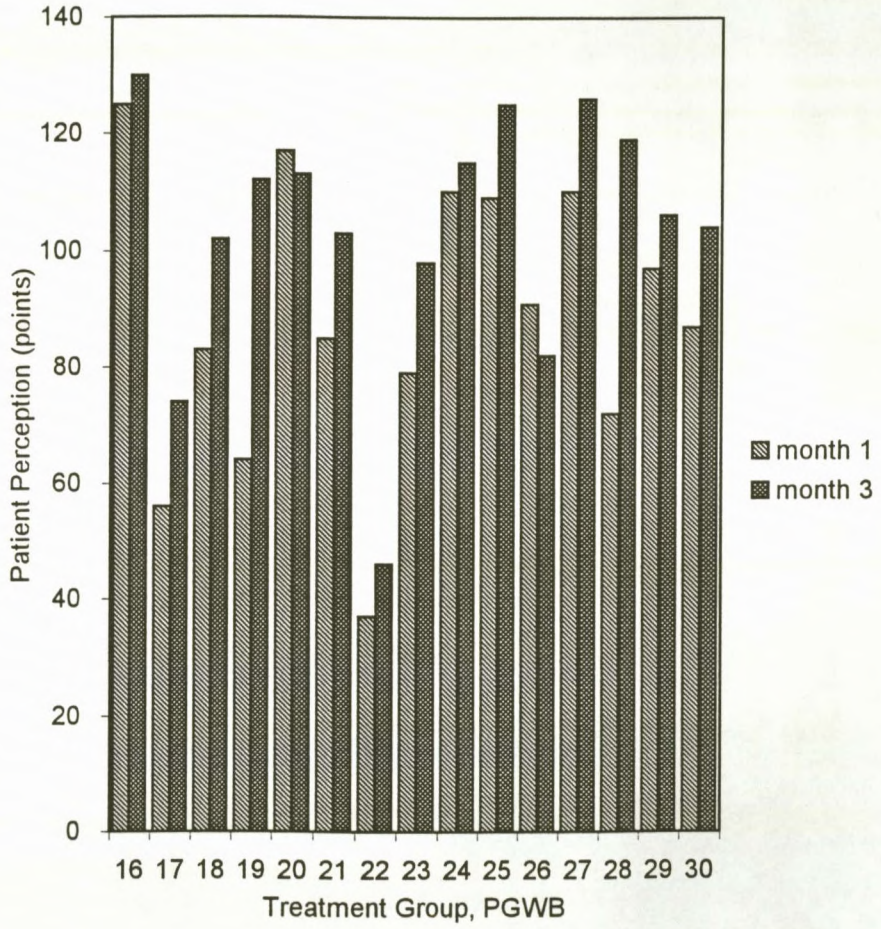


Table 4.1.4

Frequency table displaying rates of occurence for the Psychological Well-Being Index questionnaire placebo group.

Group	Improved	No change	Worsened	Total
Treatmen	13 (86.67%	0 (0.00%	2 (13.33%	15 (100.00%)

Table 4.1.5

Table showing the results of the paired T-test for the Psychological Well-Being Index placebo group.

Dimension PGWB	Month 1 Mean +/-	SD	Month 3 Mean +/-	SD	Individual diff. Mean+/-	SD	P value
Anxiety	68.000	9.000	67.000	13.352	1.000	8.856	0.669
Depression	71.200	10.339	68.867	13.768	2.333	6.422	0.181
Well-being	62.333	8.558	64.000	13.022	1.667	8.958	0.483
Health	53.267	6.319	51.933	9.968	1.333	7.771	0.517
Vitality	66.933	9.874	63.867	13.190	3.067	9.932	0.252
Self-control	41.200	6.132	40.733	7.914	0.467	6.058	0.770

The p values shown indicate that the null hypothesis could not be rejected, i.e. there was no significant difference between the initial and final scores.

Table 4.1.6

Table showing the results of the paired T-test for the Psychological Well-Being Index treatment group.

Dimension PGWB	Month 1 Mean +/-	SD	Month 3 Mean +/	SD	Individual diff. Mean+/-	SD	P value
Anxiety	65.467	16.080	73.733	17.360	-8.267	11.811	0.017
Depression	67.800	18.713	74.667	18.176	-6.867	9.899	0.018
Well-being	63.933	13.057	71.467	14.837	-7.533	7.210	0.001
Health	54.667	12.579	57.400	11.933	-5.333	8.690	0.032
Vitality	62.467	17.262	68.667	17.871	-6.200	6.668	0.003
Self-control	40.200	10.523	43.267	9.888	-3.067	6.181	0.075

The p values, with the exception of p=0.07 for self control, all indicate that the null hypothesis can be rejected i.e. there was a significant difference between the initial final scores.

Table 4.1.7

Patient Perception questionnaire (PPER) scores before and after placebo treatment.

Placebo group	Month 1	Month 3
1	91	65
2	62	27
3	39	17
4	87	32
5	36	33
6	47	59
7	56	37
8	71	114
9	37	65
10	26	28
11	72	114
12	61	85
13	31	10
14	30	3
15	50	25

Figure 4.1.3

Graph based on values in table 4.1.7 demonstrating any change in patients perception to the treatment. PPER placebo group.

Figure 4.1.3

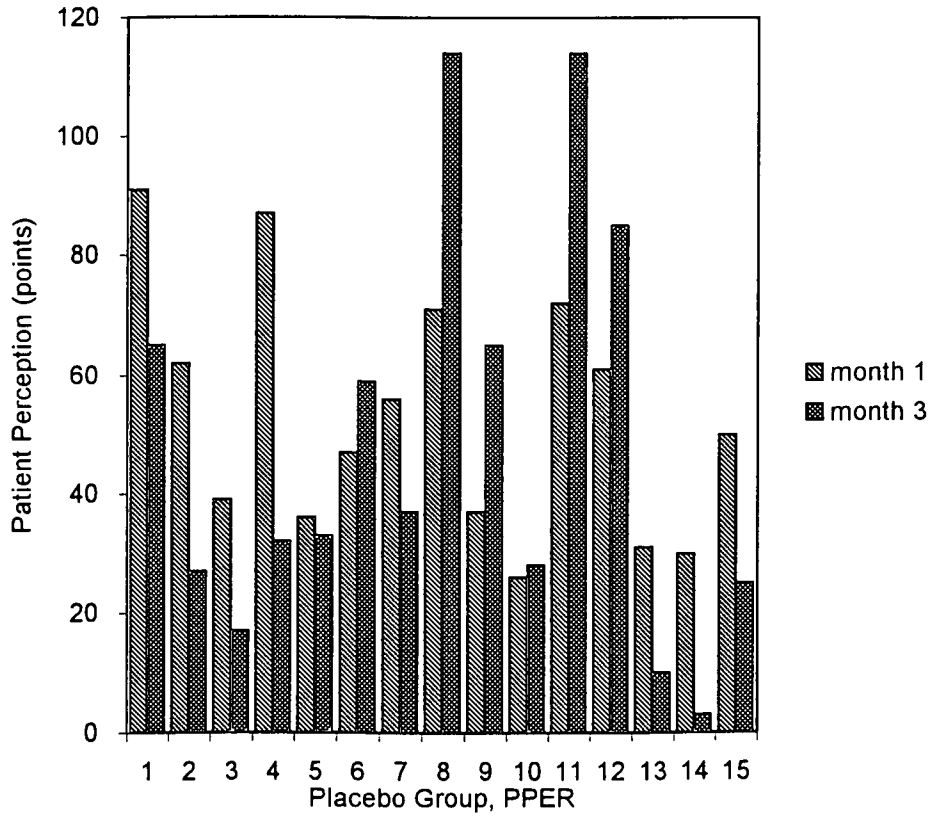


Table 4.1.8

Frequency table displaying rates of occurence for the Patient Perception questionnaire placebo group.

Group	Improved	No change	Worsened	Total
Placebo	9 (60.00%	0 (0.00%)	6 (40.00%	15 (100.00%)

Table 4.1.9

Patient Perception questionnaire (PPER) scores before and after homoeopathic treatment. Treatment group.

Treatment group	Month 1	Month 3
16	44	20
17	76	54
18	76	59
19	78	18
20	51	6
21	20	7
22	102	49
23	97	29
24	37	4
25	20	16
26	121	82
27	43	24
28	60	6
29	76	51
30	82	40

Figure 4.1.4

Graph based on values in Table 4.1.9 demonstrating any change in patients perception of the treatment. PPER treatment group

Figure 4.1.4

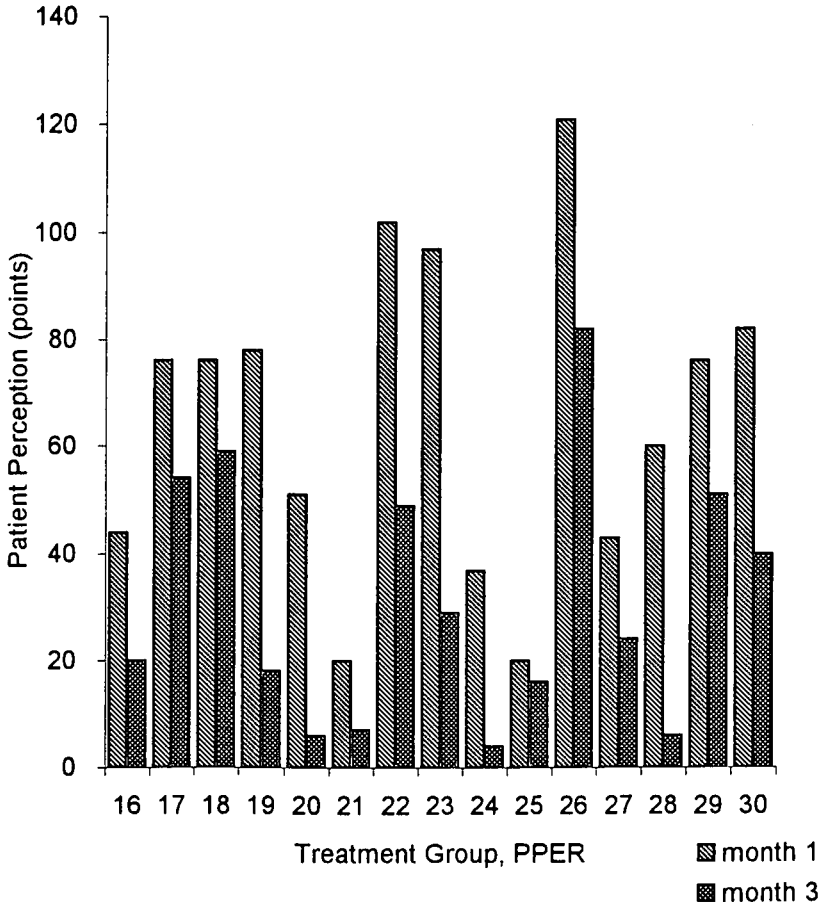


Table 4.1.10

Frequency table displaying rates of occurence for the Patient Perception questionnaire treatment group.

Group	Improved	No change	Worsened	Total
Treatment	15 (100.00%	0 (0.00%)	0 (0.00%)	15 (100.00%)

Table 4.1.11

Table showing the results of the paired T-test for the Patient Perception questionnaire placebo group.

Dimension PPER	Month 1 Mean +/-	SD	Month 3 Mean +/-	SD	Individual diff. Mean+/-	SD	P values
Vasomotor	11.733	6.670	8.133	5.705	3.600	5.275	0.019
Emotions	27.267	12.180	20.533	11.218	6.733	12.975	0.064
Other	14.067	7.601	11.600	8.441	2.467	8.774	0.295

The vasomotor symptoms p=0.019 show that the null hypothesis can be rejected, i.e. the vasomotor symptoms for the placebo group improved. The other symptoms show no statistical difference.

Table 4.1.12

Table showing the results of the paired T-test for the Patient Perception questionnaire treatment group.

Dimension PPER	Month 1 Mean +/-	SD	Month 3 Mean +/-	SD	Individual diff. Mean+/-	SD	P values
Vasomotor	14.800	11.509	6.333	5.888	8.467	7.328	0.001
Emotions	39.400	20.420	20.800	17.620	18.600	16.569	0.001
Other	17.800	11.515	9.667	7.641	8.133	5.805	0.000

All the p values shown indicate that the null hypothesis can be rejected, i.e there is a statistical difference between the initial and final scores.

Table 4.1.13

Table showing total number of hot flushes, from the hot flush score sheet, for month 1 and month three, for the placebo group.

Placebo group	Month 1	Month 3
1	220	190
2	152	48
3	0	0
4	141	0
5	134	154
6	198	201
7	202	80
8	76	181
9	50	187
10	191	94
11	72	180
12	120	186
13	72	45
14	115	0
15	217	130

Table 4.1.14

Frequency table displaying rates of occurence of hot flushes, from the hot flush score sheet, for the placebo group.

Group	Improved	No change	Worsened	Total
Placebo	8 (53.33%)	1 (6.67%)	6 (40.00%)	15 (100.00%)

Table 4.1.15

Table showing total number of hot flushes, from the hot flus score sheet, for month 1 and month 3, for the treatment group.

Treatment group	Month 1	Month 3
16	195	72
17	138	92
18	104	146
19	167	142
20	122	72
21	0	0
22	97	76
23	205	80
24	154	27
25	182	36
26	210	92
27	205	47
28	158	40
29	75	37
30	92	45

Table 4.1.16

Frequency table displaying rates of occurence of hot flushes from the hot flush score sheet, for the treatment group.

Group	Improved	No change	Worsened	Total
Treatment	13 (86.67%)	1 (6.67%)	1 (6.67%)	15 (100.00%)

4.2 HYPOTHESIS TESTING FOR SUBPROBLEM TWO

The un-paired T-test was used to compare the perception of the treatment of the placebo group against that of the treatment group for the PPER and the PGWB questionnaires.

Table 4.2.1

Table showing the results of the un-paired T-test for the Psychological Well-Being Index questionnaire.

Dimension PGWB	Month 1 Mean +/-	SD	Month 3 Mean +/-	SD	P value Month 1	P value Month 3
Anxiety	66.733	13.030	70.367	15.486	0.599	0.244
Depression	69.500	15.117	71.767	16.124	0.543	0.333
Well-being	63.133	11.039	67.733	13.959	0.694	0.154
Health	53.967	9.954	54.667	10.994	0.703	0.184
Vitality	64.700	14.062	66.267	15.706	0.392	0.410
Self-control	40.700	8.612	42.000	8.956	0.753	0.445

The p values show no significant difference between the initial and final scores, and therefore the null hypothesis cannot be rejected.

Table 4.2.2

Table showing the results of the un-paired T-test for the Patient Perception questionnaire.

Dimension PPER	Month 1 Mean +/-	SD	Month 3 Mean +/-	SD	P value Month 1	P value Month 3
Vasomotor	13.267	9.406	8.133	5.705	0.380	0.402
Emotions	33.333	16.813	20.667	14.770	0.058	-0.049
Other	15.933	9.757	10.633	8.051	0.304	0.516

The p values show no significant difference between the initial and final scores, and therefore the null hypothesis cannot be rejected.

Table 4.2.3

Table showing averages from the un-paired T-test for the Psychological General Well-Being Index placebo and treatment groups.

Dimension PGWB	Placebo group Month 1	2	3	Treatment group Month 1	2	3
Anxiety	68.0	69.1	67.0	65.5	70.1	73.7
Depression	71.2	68.4	68.9	67.8	71.3	74.7
Well-being	62.3	62.7	64.0	63.9	66.3	71.5
Health	53.3	51.7	61.9	54.7	57.7	57.4
Vitality	66.9	61.9	63.9	62.4	67.8	68.7
Self-control	41.2	42.3	40.7	40.2	42.4	43.3

Figure 4.2.1

Graph derived from the averages from the PGWB questionnaire for months 1,2,3 for Anxiety.

Figure 4.2.1

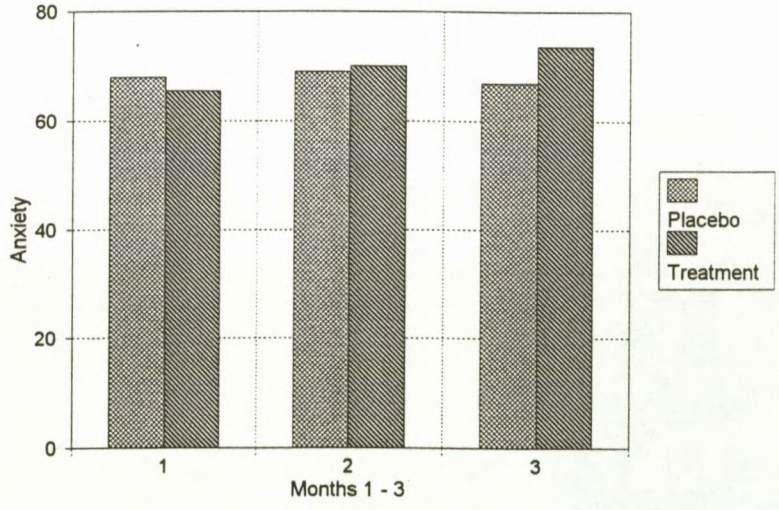


Figure 4.2.2

Graph derived from the averages from the PGWB questionnaire for months 1,2,3 for Depression.

Figure 4.2.2

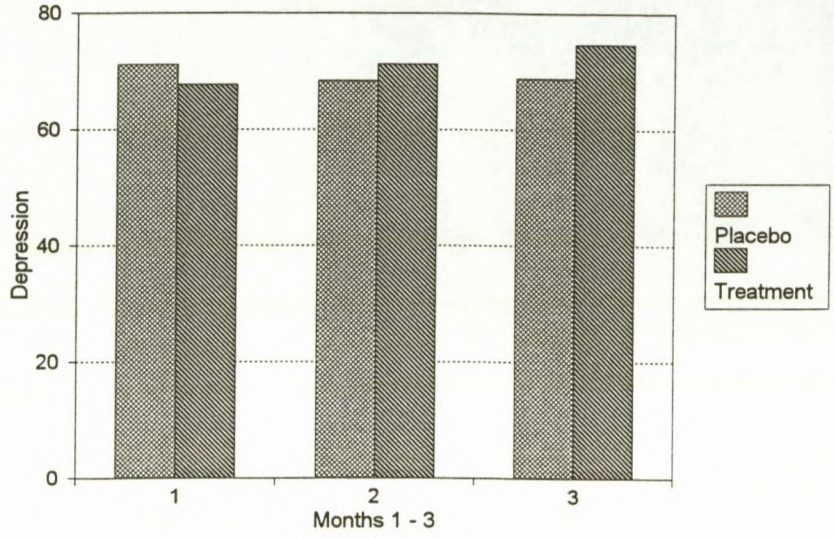


Figure 4.2.3

Graph derived from the averages from the PGWB questionnaire for months 1,2,3 for Well-being.

Figure 4.2.2

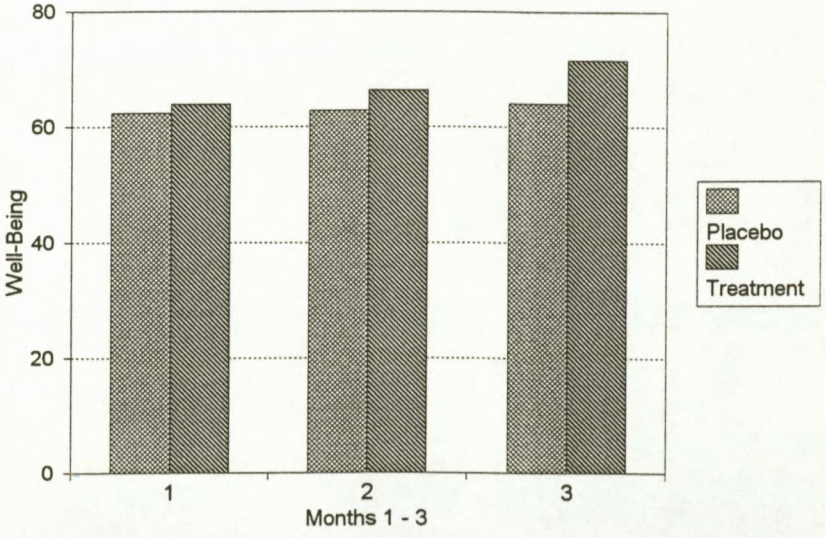


Figure 4.2.4

Graph derived from the averages from the PGBW questionnaire for months 1,2,3 for Health.

Figure 4.2.4

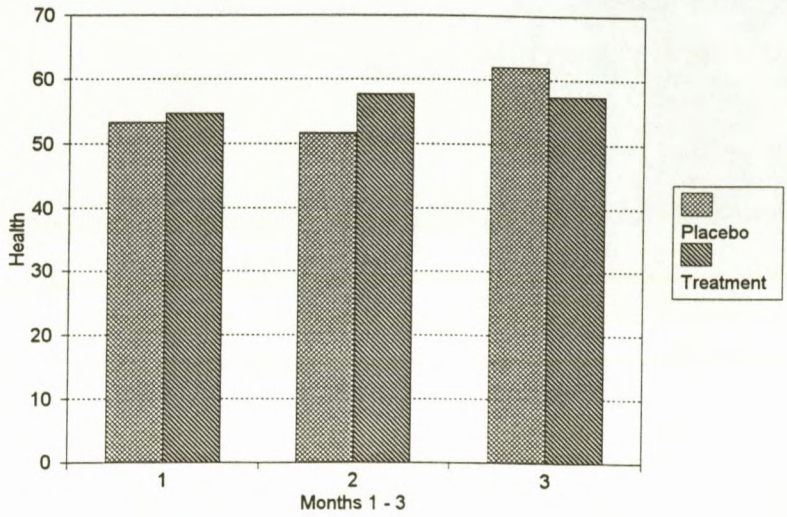


Figure 4.2.5

Graph derived from the averages from the PGWB questionnaire for months 1,2,3 for Vitality.

Figure 4.2.5

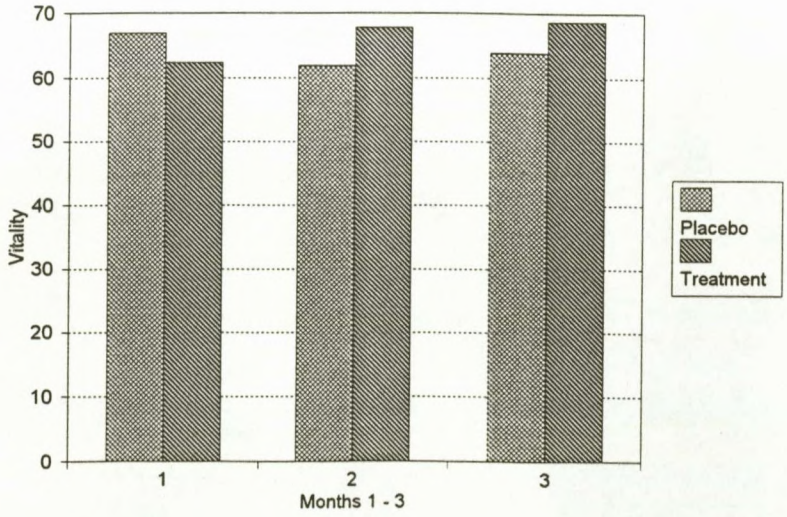


Figure 4.2.6

Graph derived from the averages from the PGWB questionnaire for months 1,2,3 for Self Control.

Figure 4.2.6

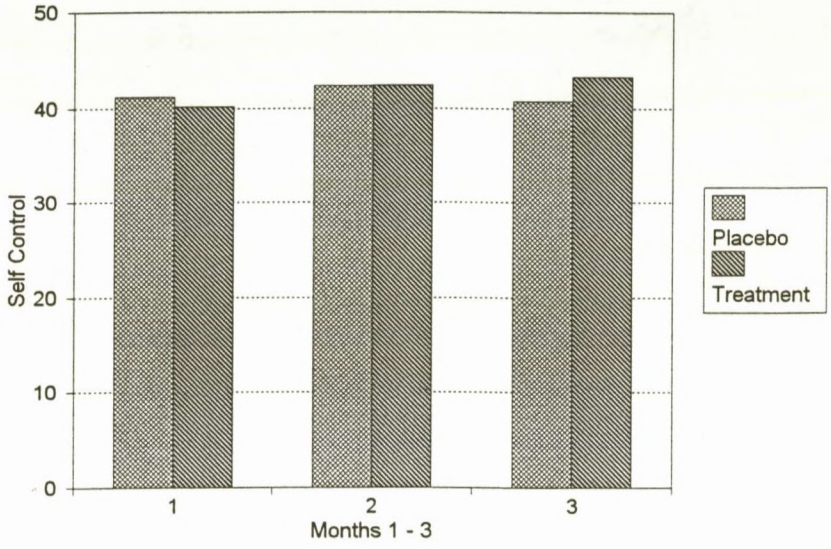


Table 4.2.4

Table showing averages from the un-paired T-test for the Patient Perception questionnaire for the treatment and placebo groups.

Dimension PPER	Placebo group month 1	2	3	Treatment group month 1	2	3
Vasomotor	11.7	7.7	8.1	14.8	7.7	6.3
Emotions	27.3	24.1	20.5	39.4	27.4	20.8
Other	14.1	14.1	11.6	17.8	11.0	9.7

Figure 4.2.7

Graph derived from the averages from the PPR Questionnaire for months 1,2,3 for Vasomotor.

Figure 4.2.7

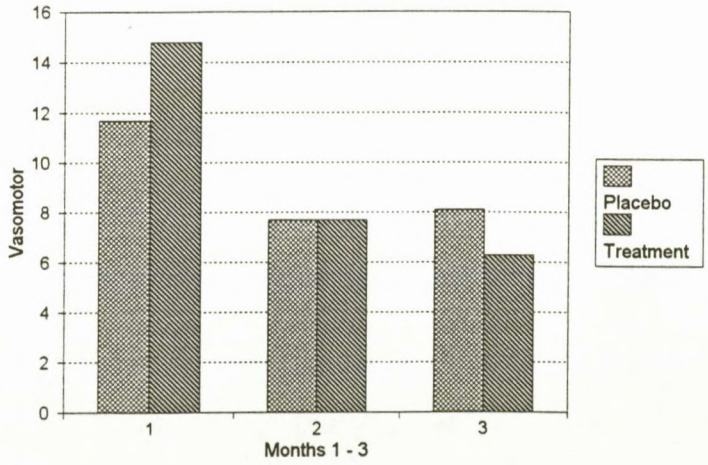


Figure 4.2.8

Graph derived from the averages from the PPR Questionnaire for months 1,2,3 for Emotions.

Figure 4.2.8

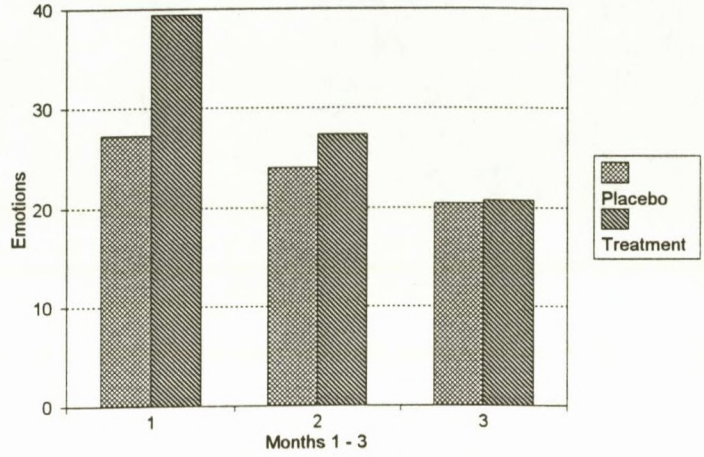
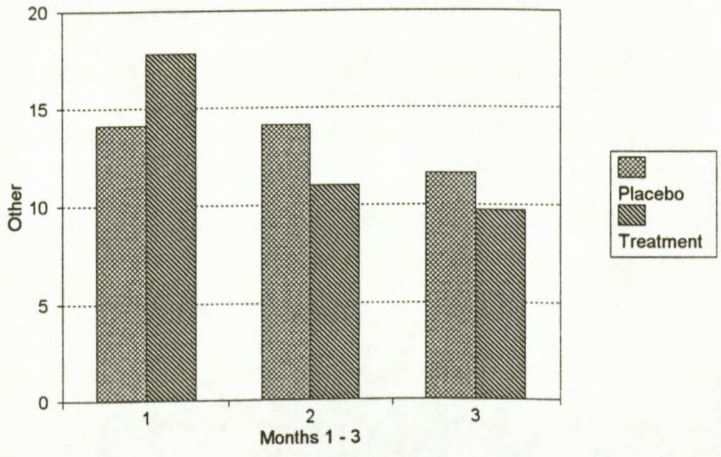


Figure 4.2.9

Graph derived from the averages from the PPR Questionnaire for months 1,2,3 for Other.

Figure 4.2.9



CHAPTER FIVE: DISCUSSION

5.1 INTRODUCTION

The problem statement aimed at determining the effectiveness of the Homoeopathic treatment of the menopause, in terms of the patients perception of the treatment. This was achieved in two ways, i.e. subproblem one and two.

SUBPROBLEM ONE : Focuses on the patients perception of the treatment via questionnaires, the Psychological General Well-Being Index (PGWB) and the Patient Perception Questionnaire (PPER).

SUBPROBLEM TWO : Focuses on the analysis and interpretation of the collected data from the questionnaires.

A sample size of thirty was randomly divided into two equal groups by a Homoeopathic pharmacist, a neutral member of the study (FRAZER 1993). The first group consisting of fifteen patients (1-15) called the placebo group received placebo medication. The second group called the treatment group (16-30) received Homoeopathic medicine. Both groups completed the questionnaires for three months. The PGWB was completed on a weekly basis and the PPER on a ten day basis. A hot flush sore sheet was

filled in, on a daily basis for three months by both groups.

5.2 SUBPROBLEM ONE

The paired T-test was used to compare the initial visit scores with the final visit scores for the PGWB and the PPER questionnaires for both the placebo and treatment groups.

5.2.1 PGWB PLACEBO GROUP

The results of the paired T-tests performed on the placebo group showed no statistical difference between the initial and final scores (Table 4.1.5). Considering the frequency of occurrence, 53.3% improved and 46.7% worsened (Table 4.1.2).

5.2.2 PGWB TREATMENT GROUP

The p values from the paired T-tests showed a significant difference between the initial and final visits for five of the symptom clusters (Table 4.1.6):

Anxiety p= 0.017

Depression p = 0.018

Well-being p = 0.001

Health p = 0.032

Vitality p = 0.003

Self control showed no significant statistical

improvement, p = 0.075 (Table 4.1.6). Considering the frequency of occurrence 86.7% improved and 13.3% worsened (Table 4.1.4).

5.2.3 PPER PLACEBO GROUP

A statistical difference was noted between the initial and final scores for the vasomotor symptoms (p = 0.019). No significant statistical difference was shown between the initial and final readings for the other symptoms (Table 4.1.11). Considering the frequency of occurrence, there was a 60% improvement and 40% worsened (Table 4.1.8).

5.2.4 PPER TREATMENT GROUP

The p values showed significant differences between the initial and final scores for all of the symptom clusters (Table 4.1.12):

Vasomotor p = 0.001

Emotions p = 0.001

Other p = 0.000

Considering the frequency of occurrence, there was a 100% improvement.

5.2.6 HOT FLUSH SCORE SHEET PLACEBO GROUP

The hot flush score sheet showed a 53.3% improvement in hot flushes for the placebo group, 6.7% did not change, and 40% worsened.

5.2.6. HOT FLUSH SCORE SHEET TREATMENT GROUP

The hot flush score sheet showed a 86.7% improvement in hot flushes for the treatment group, 6.7% did not change, and 6.7% worsened.

5.3 SUBPROBLEM TWO

In this subproblem the data captured, from the two questionnaires PGWB and PPER for the change in patients perception, of the placebo and treatment groups was analyzed. The change in patients perception of the treatment of the placebo group, was compared to that of the treatment group using the un-paired T-test. It was found with a 95% significance level that the placebo group did not significantly differ from the treatment group for each of the questionnaires (PGWB see table 4.2.1. and PPER see table 4.2.2).

5.4. CONCLUSION

5.4.1 PLACEBO GROUPS

The placebo group for the PGWB improved by 53% and for the PPER by 60%. This could have been attributed to the placebo effect. A placebo has been defined as any therapy or component of therapy that is deliberately used for its non-specific, psychological, or psycho-physiological effect, but is without specific activity for the condition being treated (Broome 1989). The proportion of placebo

respondents in particular samples may vary from 0% -100%, although the number commonly falls in the 30 - 50% range. The fact that 56% of patients in the treatment trial responded to the placebo could suggest that placebo respondents may differ significantly to non placebo respondents. Placebo reactors are more emotionally dependent, extravert, neurotic and suggestible (Broome 1989).

Therapist variables also have an influence on placebo responsivity. The confidence with which the placebo is administered appears to have an effect on its strength of action. The apparent concern with which a treatment is administered is also important (Broome 1989).
The study was a double blind so that the researcher had no idea who was in the treatment and who was in the placebo group. The two groups were therefore treated with the same confidence and concern. According to Lawson and Richards 1992 the double blind is the most valuable tool for assessing the merits of a form of treatment.

It has been proposed that reduction of anxiety is responsible for certain placebo effects, for example, ceasing to worry about a symptom may reduce attention to it and hence its perceptual salience (Pennebaker 1982).

Other factors contributing to the improvement could have been the possibility of patients filling in the questionnaire incorrectly.
Fatigue, stress and anxiety levels could also have been lower during the trial period thus increasing the coping mechanisms (Broome 1989).

The placebo group worsened by 46% for the PGWB and 40% for the PPER. This could be the result of not being a placebo reactor (Broome 1989) as well as incorrectly answered questionnaires.

5.4.2 TREATMENT GROUPS

The treatment group for the PGWB improved by 86% and for the PPER by 100%. This could be due to the Homoeopathic medication, the placebo effect, or a combination of the two.

The most common menopausal symptoms experienced to some degree by 80% of women are vasomotor ones - hot flushes, sweats, palpitations and headaches (Wilson 1992). All these symptoms for the PPER questionnaire improved (Table 4.2.4). This is in agreement to other studies (Coope, and Campbell 1981). The specific symptom of hot flushes showed an improvement, which was very positive as the most effective means for controlling hot flushes are exogenous

oestrogens. Because oestrogen therapy carries with it certain metabolic risks, it is contraindicated in some women . There is therefore a real need for suitable non - hormonal methods controlling hot flushes (Notelovitz 1982).

The symptom improvement could have been due to a improvement in lifestyle with sensible nutrition, regular exercise and cutting down on alcohol and cigarettes (Wilson 1992). The improvement in the symptoms such as sleep and headaches could have been secondary to amelioration of hot flushes and sweating which occur more frequently at night and disrupt the sleep (Wiklund 1992).

Emotional changes are commonly complained of by women experiencing the menopause (Wilson 1992). The PGWB questionnaire covered the psychological symptoms experienced by the women, these included sections on anxiety, depression, well-being, self control and vitality. All of these symptoms improved (Table 4.2.3). This may have been due to altered beliefs about the menopause during the treatment, as it is known that beliefs held before the menopause may influence the individuals emotional symptoms (Wilson 1992).
The interaction of the doctor and patient plays an important role as the behavior of the therapist may have

subtle yet powerful influences on the patient (Broome 1989). The patient is assured that all is well thus alleviating their symptoms.
The questionnaires could also have been incorrectly filled in.

The treatment group for the PGWB questionnaire worsened by 13.3% (Table 4.1.4), the treatment group for the PPER questionnaire had no worsening of symptoms (Table 4.1.8). The results for the PGWB could be due to the patient not complying with the rules and regulations of storing, time and method of taking the medication. The wrong medicine could have been prescribed and the questionnaires could have been filled in incorrectly.

Experimentally the treatment and placebo groups did not show a significant statistical change between themselves in the improvement of the menopausal symptoms. It is significant however, that the treatment group did show a higher percentage improvement over the placebo group. The PGWB showed a 33% greater improvement over the placebo group (Table 4.1.2 and 4.1.4), and the PPER showed a 40% greater improvement over the placebo group (Table 4.1.8 and 4.1.12).

5.5 RECOMMENDATIONS

Many previous studies have used psychometrically undocumented measures, making comparisons between different populations and / or studies difficult. In trials the ability of a measure to detect treatment induced changes over time is difficult, and the only way this can be tested is within the framework of a clinical trial. Since no single questionnaire appears to encompass the range of features requiring evaluation for the menopause the use of a battery constitutes a better approach (Wiklund 1992). Two questionnaires were used in the clinical study on menopause. They covered the psychological (PGWB) and the physical (PPER) symptoms of menopause.

A battery needs to include both scientific and generic measures in order that both scope and responsiveness is achieved (Wiklund 1992).

In order that the study on menopause would have greater scope other questionnaires would need to include factors such as employment, family life, social life and holidays all of which influence the menopause (Wiklund 1992). Other factors such as cigarette, alcohol and meat consumption should be included, the effect of which has been well documented (Torgerson 1993).

It is recommended that further trials be done over a longer time period and with a larger sample group. Another

alternative to the use of selected Homoeopathic remedies would be to use a single remedy eg. Lachesis versus placebo. It might produce significant results (Recommendation by Dr A.Horvilleur president of the International Medical Homoeopathic organization).

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APPENDIX A

Patient perception questionnaire.

Psychological general well-being index questionnaire.

Hot flush score sheet.

Patient consent form.

TECHNIKON NATAL

DEPARTMENT OF HOMOEOPATHY

QUESTIONNAIRE ON PATIENT PERCEPTION

INSTRUCTIONS :

1. Plese answer all questions.

2. Read each question carefully before answering.

   Each question has been graded.

   0 = No symptoms
   3 = Slight symptoms
   6 = Moderate symptoms
   9 = Severe symptoms

3. Answer each question by circling the appropriate number.

4. Answer all questions honestly.

5. This information is strictly confidential and will be used for research purposes only.

NAME:..... .....

DATE:.... ...

MENOPAUSAL SYMPTOM QUESTIONNAIRE

The rating scales below are designed to measure the degree to which you suffer from the following symptoms:
Please circle the number on the scale which describes the severity of your symptoms.

1. HOT FLUSHES

0 1 2 3 4 5 6 7 8 9 10

none severe

2. SWEATING

0 1 2 3 4 5 6 7 8 9 10

none severe

3. MENSTRUAL IRREGULARITY

0 1 2 3 4 5 6 7 8 9 10

none severe

4. VAGINAL DRYNESS

0 1 2 3 4 5 6 7 8 9 10

none severe

5. HEADACHES

0 1 2 3 4 5 6 7 8 9 10

none severe

6. PALPITATIONS

0 1 2 3 4 5 6 7 8 9 10

none severe

7. JOINT PAIN

0 1 2 3 4 5 6 7 8 9 10

none severe

8. BACKACHE

0 1 2 3 4 5 6 7 8 9 10

none severe

9. SHORTNESS OF BREATH

0 1 2 3 4 5 6 7 8 9 10

none severe

10. PAINFUL INTERCOURSE

0 1 2 3 4 5 6 7 8 9 10

none severe

11. VERTIGO

0 1 2 3 4 5 6 7 8 9 10

none severe

12. DEPRESSION

0 1 2 3 4 5 6 7 8 9 10

none severe

13. INSOMNIA

0 1 2 3 4 5 6 7 8 9 10

none severe

14. LACK OF ENERGY

0 1 2 3 4 5 6 7 8 9 10

none severe

15. LOSS OF APPETITE

0 1 2 3 4 5 6 7 8 9 10

none severe

16. IRRITABILITY

0 1 2 3 4 5 6 7 8 9 10

none severe

17. NERVOUSNESS

0 1 2 3 4 5 6 7 8 9 10

none severe

18. DECREASED CONCENTRATION

0 1 2 3 4 5 6 7 8 9 10

none severe

19. DECREASED LIBIDO

0 1 2 3 4 5 6 7 8 9 10

none severe

20. OTHER SYMPTOMS

PSYCHOLOGICAL GENERAL WELL-BEING INDEX

Please read this carefully

On the following pages you will find some questions asking about how you have been feeling in yourself during the past week. Please answer these questions as honestly as you can.

Do not consult anyone else about your answers just say what you think best applies to you.

PGWB(eng)

1. How have you been feeling in general? (DURING THE PAST WEEK)

- ☐ In excellent spirits
- ☐ In very good spirits
- ☐ In good spirits mostly
- ☐ I have been up and down in spirits a lot
- ☐ In low spirits mostly
- ☐ In very low spirits

2. Have you been bothered by any illness, pains or fears about your health? (DURING THE PAST WEEK)

- ☐ Every day
- ☐ Almost every day
- ☐ About half of the time
- ☐ Now and then, but less than half the time
- ☐ Rarely
- ☐ None of the time

3. Did you feel depressed? (DURING THE PAST WEEK)

- ☐ Yes - to the point that I felt like taking my life
- ☐ Yes - to the point that I did not care about anything
- ☐ Yes - very depressed almost every day
- ☐ Yes - quite depressed several times
- ☐ Yes - a little depressed now and then
- ☐ No - never felt depressed at all

4. Have you been in firm control of your actions, thoughts or feelings? (DURING THE PAST WEEK)

- ☐ Yes, definitely so
- ☐ Yes, for the most part
- ☐ Generally so
- ☐ Not too well
- ☐ No, and I am somewhat disturbed
- ☐ No, and I am very disturbed

5. Have you been bothered by your nerves? (DURING THE PAST WEEK)

- ☐ Extremely so - to the point where I could not work or take care of things
- ☐ Very much so
- ☐ Quite a bit
- ☐ Some - enough to bother me
- ☐ A little
- ☐ Not at all

6. How much energy or vitality did you have? (DURING THE PAST WEEK)

- ☐ Very full of energy
- ☐ Fairly energetic most of the time
- ☐ My energy level varied quite a bit
- ☐ Generally low in energy
- ☐ Very low in energy most of the time
- ☐ No energy at all - I felt drained, sapped

7. Have you felt downhearted and sad? (DURING THE PAST WEEK)

- ☐ None of the time
- ☐ A little of the time
- ☐ Some of the time
- ☐ A good bit of the time
- ☐ Most of the time
- ☐ All of the time

8. How tense have you been? (DURING THE PAST WEEK)

- ☐ Extremely tense, most or all of the time
- ☐ Very tense most of the time
- ☐ Not generally tense, but did feel fairly tense a few times
- ☐ I felt a little tense a few times
- ☐ My general tension level was quite low
- ☐ I never felt tense or any tension at all

9. How happy, pleased or satisfied have you been with your personal life? (DURING THE PAST WEEK)

- ☐ Extremely happy - could not have been more satisfied or pleased
- ☐ Very happy most of the time
- ☐ Generally happy most of the time
- ☐ Sometimes fairly happy, sometimes fairly unhappy
- ☐ Generally dissatisfied, unhappy
- ☐ Very dissatisfied or unhappy most or all the time

10. Did you feel well enough to do the things you like to do or had to do? (DURING THE PAST WEEK)

- ☐ Yes - definitely so
- ☐ For the most part
- ☐ Health problems limited me in some important ways
- ☐ I was only healthy enough to take care of myself
- ☐ I needed some help in taking care of myself
- ☐ I needed someone to help me with most or all of the things I had to do

11. Have you felt sad? Discouraged or hopeless, so much that you wondered if life was worthwhile? (DURING THE PAST WEEK)

- ☐ Extremely so - to the point that I have just about given up
- ☐ Very much so
- ☐ Quite a bit
- ☐ Some - enough to bother me
- ☐ A little bit
- ☐ Not at all

12. Have you been waking up feeling fresh and rested? (DURING THE PAST WEEK)

- ☐ None of the time
- ☐ A little of the time
- ☐ Some of the time
- ☐ A good bit of the time
- ☐ Most of the time
- ☐ All of the time

13. Have you had any worries or fears about your health? (DURING THE PAST WEEK)

- ☐ Yes, very much so and I am very worried
- ☐ Some and I am quite worried
- ☐ Some and I have been a little worried
- ☐ Some - but not enough to be worried about
- ☐ Only a little
- ☐ Not at all

14. Have you seriously thought you might be losing control over your thoughts and actions? (DURING THE PAST WEEK)

- ☐ Not at all
- ☐ Only a little
- ☐ Some - but not enough to be concerned or worried about
- ☐ Some and I have been a little concerned
- ☐ Some and I am quite concerned
- ☐ Yes, very much so and I am very concerned

15. Has your daily life been filled with things that interest you? (DURING THE PAST WEEK)

- ☐ None of the time
- ☐ A little of the time
- ☐ Some of the time
- ☐ A good bit of the time
- ☐ Most of the time
- ☐ All of the time

16. How active and vigorous have you felt? (DURING THE PAST WEEK)

- ☐ Very active, vigorous every day
- ☐ Mostly active, vigorous - never really dull, sluggish
- ☐ Fairly active, vigorous - seldom dull, sluggish
- ☐ Fairly dull, sluggish - seldom active, vigorous
- ☐ Mostly dull, sluggish - never really active, vigorous
- ☐ Very dull, sluggish every day

17. Have you been anxious? Worried or upset? (DURING THE PAST WEEK)

- ☐ Extremely so - to the point of being sick or almost sick
- ☐ Very much so
- ☐ Quite a bit
- ☐ Some - enough to bother me
- ☐ A little bit
- ☐ Not at all

18. Have you felt stable and sure of yourself? (DURING THE PAST WEEK)

- ☐ None of the time
- ☐ A little of the time
- ☐ Some of the time
- ☐ A good bit of the time
- ☐ Most of the time
- ☐ All of the time

19. How relaxed have you felt? (DURING THE PAST WEEK)

- ☐ Felt relaxed and at ease the whole time
- ☐ Felt relaxed and at ease most of the time
- ☐ Generally felt relaxed but at times felt fairly high strung
- ☐ Generally felt high strung but at times felt fairly relaxed
- ☐ Felt high strung, tight, or keyed-up most of the time
- ☐ Felt high strung, tight, or keyed-up the whole week

20. Have you been cheerful? (DURING THE PAST WEEK)

- ☐ None of the time
- ☐ A little of the time
- ☐ Some of the time
- ☐ A good bit of the time
- ☐ Most of the time
- ☐ All of the time

21. Have you felt tired? Worn out or exhausted? (DURING THE PAST WEEK)

- ☐ None of the time
- ☐ A little of the time
- ☐ Some of the time
- ☐ A good bit of the time
- ☐ Most of the time
- ☐ All of the time

22. Have you been under any stress or pressure? (DURING THE PAST WEEK)

- ☐ Yes - almost more than I could bear or stand
- ☐ Yes - quite a bit of pressure
- ☐ Yes, some - more than usual
- ☐ Yes, some - but about usual
- ☐ Yes - a little
- ☐ Not at all

NAME: _____

Please record the number of hot flushes over a 24 Hour period. Write 0 for no flushes.

DAYS	MONTH ONE	MONTH TWO	MONTH THREE
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			
31			

PATIENT CONSENT FORM

FULL NAME
ADDRESS
TELEPHONE NUMBER
AGE

Thank you for considering to be part of this study. The fifth year Homoeopathic students are required to complete a thesis as partial fulfilment of their Masters Diploma in Homoeopathy. The thesis is undertaken with the purpose of adding to the Homoeopathic pool of knowledge and promoting Homoeopathy.

The menopause is a period of intense hormonal adjustments which can be accompanied by considerable discomfort. The menopausal complaints often become so severe that they become a syndrome which requires specific treatment. If treated, many symptoms and complications can be avoided. Conventional therapy involves hormone substitution, prescription of sedatives and tranquillisers. This constitutes replacement therapy which may correct the superficial deficiency, but does not the underlying imbalance. This leads to the dependence of general emotional and physical health on substances which the therapy entails. These therapies are costly, have undesired side-effects, and cause iatrogenic damage.

Not much research has been accomplished in the homoeopathic treatment of menopause. It is the aim of this study to see if homoeopathy has a place for treating menopause.
Homoeopathy will offer a more economical alternative to treating menopause and there are no known side-effects, although a slight aggravation may be experienced by a few patients.

In order to ensure that this research complies with the scientific method only certain people will be accepted as part of the research. The sample of 30 patients used in this study will be randomly drawn from the population in Natal. Possible candidates must qualify in the following cases:-

1) Patients must be from the greater Durban environment.
2) Patients must not be taking any hormone replacements.
3) Patients must be going through natural menopause, i.e. not have had a hysterectomy and still have their ovaries intact.
4) The patient will be required to undergo a gynaecological exam by a registered gynaecologist.

5) The patient will have a complete case history taken.
6) The patient will be required to take the medicine as stipulated by the practitioner.
7) The patient must complete the questionnaires as and when necessary.
8) Of the thirty patients, half will receive empathic treatment and half will receive placebo.

Patient/practitioner confidentiality will be strictly adhered to.

I, ... do hereby agree to abide by the delimitations and conditions set out in the above document.

....

Signature Date

APPENDIX B

CASE HISTORY

Patients name: Date:

Age: Marital status:

Occupation: Address:

Tel. no:

Past medical history:

Childhood illnesses

Adult illnesses

Psychiatric illnesses

Operations

Allergies:

Medication:

Social history:

Exercise and leisure activities

Tobacco and alcohol consumption

Family history:

Data on the family on occurrence of any conditions.

Main complaint:

Pain, duration, radiation, onset, modalities.

Systems review:

Head; headaches, vertigo.

Eyes; vision, pain, redness.

Ears; Hearing, tinnitus, infection.

Nose and sinuses; frequent colds, discharge, hayfever, sinus trouble.

Mouth and throat; frequent sore throats, hoarseness, condition of teeth.

Neck; swollen glands, goitre, stiffness.

Respiratory; cough, shortness of breath, pain.

Cardiac; blood pressure, murmurs, chest pain, palpitations.

Gastrointestinal; heartburn, appetite (food cravings and aversions), nausea, vomiting, frequency of bowel movements, abdominal pain, liver, gallbladder, pancreas.

Urinary; burning, pain, frequency, incontinence.

Genitoreproductive; age at menarche, menstrual regularity, duration of menses, dysmenorrhoea, age at menopause, menopausal symptoms, hot flushes, sweating, discharge, vaginal dryness, number of pregnancies, sexual interest, breast lumps or discomfort.

Peripheral vascular; leg cramps, varicose veins.

Musculoskeletal; joint pain, backache, stiffness.

Neurologic; fainting, seizures, paralysis, numbness, tingling, tremors.

Haematologic; anaemia, easy bruising, bleeding.

Endocrine; thyroid, heat or cold intolerance, sweating, excessive thirst.

Sleep patterns; insomnia

Psychiatric; nervousness, irritability, depression, decreased concentration, attitudes to menopause, life stresses, past life experiences, coping mechanisms.

Physical examination:

Vital signs; pulse, blood pressure, respiratory rate.

Head, eyes, ears, nose, sinuses, mouth.

Neck, pharynx.

Posterior thorax and lungs.

Breasts, axillae.

Abdomen.

Inguinal area.

Musculoskeletal system.

APENDIX C

PGWB month 1, week 1, placebo group.

PGWB month1, week 1, treatment group.

PGWB month 3, week 3, placebo group.

PGWB month 3, week 3, treatment group.

PPER month1, week 1, placebo group.

PPER month 1, week 1, treatment group.

PPER month 3, week 3, placebo group.

PPER month 3, week 3 , treatment group.

PGWB month 1, week 1, placebo group questionnaire scores.

Placebo group	Questionnaire number			****											****							Row sum
	1	2	3	4	5	6	7	8	9	10	11	12	14	15	16	17	18	19	20	21	22	
1	3	3	5	3	3	3	5	2	3	4	3	2	3	3	4	4	4	3	4	3	2	74
2	4	6	5	6	6	5	6	4	4	4	5	4	3	2	4	6	5	5	4	5	6	105
3	4	6	5	6	4	4	5	2	5	6	6	2	6	5	4	6	5	4	5	3	6	105
4	3	4	4	3	4	4	4	4	3	4	4	3	3	4	3	3	3	3	3	4	4	78
5	5	4	5	4	6	5	3	4	4	6	6	5	5	4	6	5	5	4	5	5	6	107
6	3	4	4	4	4	4	5	2	1	5	3	3	4	4	5	2	3	2	4	4	1	76
7	3	6	5	6	6	5	6	4	4	6	5	5	6	6	5	5	6	5	5	5	2	112
8	4	6	4	5	4	4	3	3	6	6	5	4	5	4	5	4	4	4	4	3	4	96
9	3	4	5	4	6	3	4	3	5	5	6	5	6	5	4	5	4	5	5	5	4	99
10	3	3	5	3	3	3	5	2	3	4	3	2	3	3	4	4	4	3	4	3	2	74
11	6	5	5	4	5	4	4	3	4	6	6	5	5	5	4	5	4	4	4	4	3	99
12	3	5	5	3	5	3	5	5	3	5	4	5	6	4	4	4	5	5	6	3	4	97
13	4	2	5	4	4	4	4	4	3	5	6	5	5	5	4	4	4	3	5	6	3	91
14	5	5	5	4	5	5	5	4	4	4	5	4	6	5	4	3	4	4	5	5	5	101
15	4	4	5	5	5	4	4	3	3	5	5	3	5	3	3	5	3	4	5	4	2	88

PGWB month 1, week 1, treatment group questionnaire scores.

Treatment group	1	2	3	**** 4	5	6	7	8	9	10	11	12	14	15	**** 16	17	18	19	20	21	22	Row sum
											Questionnaire number											
16	5	6	6	6	6	5	5	6	6	6	6	5	6	6	5	5	6	5	6	6	6	125
17	1	2	4	3	3	2	2	2	2	5	2	1	5	3	2	2	1	2	3	2	2	56
18	3	4	4	5	5	3	4	4	2	5	5	1	4	4	4	3	5	4	3	4	3	83
19	3	5	4	3	2	4	4	1	4	4	5	1	2	3	3	2	4	3	2	2	1	64
20	4	6	6	5	5	5	6	6	5	6	6	5	6	5	5	5	5	5	5	5	6	117
21	4	6	5	5	3	3	3	2	3	5	5	5	3	5	3	3	4	3	5	2	2	85
22	1	2	1	1	2	1	1	1	3	2	1	1	3	2	3	2	3	2	1	1	1	37
23	3	4	5	2	3	4	3	3	3	4	4	4	5	5	3	4	4	4	4	3	2	79
24	4	4	6	6	6	5	5	4	4	6	6	4	6	5	5	5	5	5	4	5	5	110
25	4	5	5	6	5	5	4	4	6	6	4	4	6	5	4	5	6	6	5	4	5	109
26	5	5	5	5	5	5	6	3	4	4	6	6	4	4	2	3	5	2	5	2	2	91
27	5	6	6	6	6	4	5	4	4	5	6	5	6	5	4	5	5	5	5	5	3	110
28	5	5	4	2	2	4	3	2	2	5	4	3	3	5	3	2	4	2	3	4	2	72
29	3	5	5	6	5	4	4	4	4	6	6	4	5	5	5	2	5	4	4	4	2	97
30	4	4	6	4	4	5	6	2	4	5	5	3	5	4	4	3	3	2	3	4	2	87

PGWB month 3, week 4, placebo group questionnaire scores.

Placebo group	Questionnaire number			****											****								Row sum
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	
1	4	6	5	4	6	3	4	4	4	4	4	3	3	4	4	5	4	5	5	4	4	5	94
2	4	6	5	6	5	5	5	4	4	6	6	5	6	5	5	5	5	5	5	5	6	6	114
3	5	4	6	6	6	4	6	4	4	5	5	5	6	6	4	4	5	5	4	4	4	6	108
4	3	4	4	3	3	3	3	4	2	4	2	2	3	3	4	4	4	4	4	3	5	2	73
5	3	5	5	5	5	4	3	4	3	5	5	3	5	5	4	3	4	4	4	5	3	4	91
6	1	2	3	3	2	2	4	2	1	5	3	2	2	3	5	4	3	3	2	2	3	1	58
7	3	3	5	4	4	6	4	5	6	6	5	4	4	5	5	5	4	5	5	4	3	2	97
8	6	5	5	4	5	4	5	5	6	6	4	5	6	5	6	5	5	5	4	4	5	6	111
9	2	2	3	3	2	3	3	3	3	4	3	2	3	4	4	2	3	3	3	2	3	2	62
10	4	6	5	4	6	3	4	4	4	4	4	3	3	4	4	5	4	5	5	4	4	5	94
11	6	6	5	5	4	5	4	5	5	6	5	4	5	5	6	5	5	2	3	4	4	3	102
12	5	4	5	4	5	4	4	4	5	4	4	4	4	6	4	3	5	4	4	4	4	4	94
13	5	5	5	4	4	5	5	6	5	5	3	5	4	6	6	5	4	5	4	5	5	5	106
14	4	4	3	5	4	5	5	4	5	6	5	4	3	4	5	6	4	5	4	5	4	4	98
15	5	5	6	5	5	5	5	4	4	6	6	5	5	5	5	5	5	5	4	5	5	4	109

PGWB month 3, week 4,treatment group questionnaire scores.

Treatment group	Questionnaire number			****												****							Row sum
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	
16	6	6	6	6	6	5	6	6	6	6	6	6	6	6	6	5	6	6	6	6	6	6	130
17	4	5	4	4	3	4	4	2	3	5	3	1	5	5	3	3	2	3	3	3	3	2	74
18	3	4	4	5	6	4	5	4	4	5	6	4	6	6	4	4	5	5	4	5	4	5	102
19	5	5	6	6	6	5	4	5	4	6	5	5	5	6	5	4	5	6	6	5	4	4	112
20	5	6	6	6	6	5	5	4	4	6	6	6	6	6	5	5	4	5	5	4	4	4	113
21	4	5	5	4	5	5	6	4	4	5	4	5	4	5	4	5	5	5	5	5	5	4	103
22	2	2	2	1	1	2	2	1	1	3	2	2	3	2	2	3	3	2	2	3	2	3	46
23	5	5	5	5	5	4	4	2	4	3	4	5	5	5	5	5	5	4	5	5	5	3	98
24	5	6	6	5	5	6	5	5	6	6	5	5	6	5	5	5	5	5	5	4	5	5	115
25	5	5	6	6	6	5	6	6	5	6	6	5	5	6	6	6	6	6	6	6	5	6	125
26	5	4	5	4	5	2	5	4	4	3	6	1	3	3	3	2	5	3	4	3	4	4	82
27	5	5	6	6	6	5	6	6	5	6	6	5	5	6	6	6	6	6	6	6	6	6	126
28	5	5	6	6	6	5	6	5	5	6	6	5	6	6	5	5	6	5	5	5	5	5	119
29	5	5	4	5	5	6	5	4	5	5	5	4	5	5	4	5	4	5	5	5	4	6	106
3	4	4	5	5	5	5	5	5	4	4	5	5	5	6	5	5	4	5	6	5	4	3	104

PPER month 1,1st 10 days placebo group questionnaire scores.

Placebo group	Questionnaire number 1	2	3	**** 4	5	6	7	8	9	10	11	12	13	14	15	**** 16	17	18	19	Row sum
1	10	10	0	0	5	6	8	1	5	0	10	3	2	9	0	7	5	9	1	91
2	6	6	0	0	5	0	6	0	0	0	0	3	2	0	4	3	10	10	7	62
3	0	0	4	0	0	1	4	0	2	0	0	3	8	1	0	3	5	3	5	39
4	6	4	0	10	6	6	5	5	3	0	3	6	8	5	4	4	4	8	0	87
5	6	6	0	2	5	0	0	3	0	0	0	1	3	0	0	2	0	3	5	36
6	8	0	0	0	0	0	4	7	0	0	5	0	5	5	0	6	6	0	1	47
7	8	6	3	0	5	0	3	2	8	0	5	0	0	0	5	6	5	0	0	56
8	3	3	3	5	2	4	3	7	3	1	5	4	2	5	2	3	5	7	4	71
9	2	2	0	0	6	4	4	3	2	0	1	1	1	3	0	1	2	2	3	37
10	8	3	0	0	0	0	6	0	3	0	0	0	0	0	0	4	0	2	0	26
11	3	3	3	6	2	4	3	7	3	1	5	4	2	5	2	3	5	7	4	72
12	5	5	3	0	9	0	3	0	6	2	0	4	2	3	0	7	0	2	10	61
13	3	3	0	2	0	0	8	0	3	0	0	2	0	0	0	3	3	4	0	31
14	5	4	0	0	3	2	2	3	0	0	0	0	0	5	0	0	2	2	2	30
15	10	7	0	0	1	2	2	2	2	0	2	1	9	3	0	2	3	4	0	50

PPER month 1,1st 10 days treatment group questionnaire scores.

Treatment group	Questionnaire number			****											****					Row sum
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	
16	7	4	0	5	0	0	3	1	1	0	10	1	0	0	0	1	0	7	4	44
17	5	5	0	0	10	4	0	0	4	0	0	10	3	10	0	10	10	5	0	76
18	4	4	5	5	5	3	7	5	3	0	2	5	2	6	0	7	2	8	3	76
19	6	8	0	0	0	6	1	0	4	0	4	7	6	6	4	10	8	8	0	78
20	5	2	0	0	0	1	8	0	0	0	0	3	2	3	0	10	10	5	2	51
21	0	4	0	0	0	0	5	0	2	0	0	0	0	3	0	1	2	3	0	20
22	4	0	2	0	2	5	2	2	6	6	5	10	9	9	9	4	9	9	9	102
23	8	8	3	7	8	9	9	5	1	3	2	8	4	5	6	4	3	4	0	97
24	6	5	0	8	2	2	3	0	0	0	0	0	8	0	0	2	0	1	0	37
25	7	4	0	4	0	0	1	0	0	0	0	0	2	2	0	0	0	0	0	20
26	9	9	0	5	5	8	10	8	10	5	8	0	10	10	0	5	3	8	8	121
27	9	8	0	4	8	0	2	0	0	0	0	0	2	2	0	2	1	2	3	43
28	6	5	0	0	6	5	0	5	0	0	0	5	4	4	0	6	6	8	0	60
29	3	3	0	5	2	0	10	6	1	7	0	3	8	5	2	8	2	4	7	76
30	4	1	7	6	2	0	7	2	5	3	7	6	5	5	0	7	5	4	6	82

PPER month 3,last 10 days placebo group questionnaire scores.

Placebo group	1	2	3	**** 4	5	6	7	8	9	10	11	12	13	14	15	**** 16	17	18	19	Row sum
								Questionnaire number												
1	9	9	0	0	6	1	8	5	0	0	1	2	0	9	0	6	1	8	0	65
2	2	1	0	0	4	0	0	0	0	0	0	1	0	2	0	3	3	5	6	27
3	0	0	0	0	2	1	0	0	1	0	1	1	3	1	0	1	1	3	2	17
4	0	2	0	2	2	3	2	2	3	0	1	3	2	2	0	2	2	4	0	32
5	6	4	0	1	4	1	0	2	1	1	0	0	4	2	0	1	2	2	2	33
6	9	0	0	0	0	0	6	4	7	0	0	7	0	6	0	6	7	7	0	59
7	3	4	0	0	1	9	1	0	5	0	0	4	0	0	4	4	2	0	0	37
8	7	8	5	7	3	6	4	8	3	5	8	3	7	9	3	6	8	9	5	114
9	8	7	0	0	8	3	5	4	3	0	0	6	4	5	0	2	4	3	3	65
10	4	2	0	3	4	3	0	0	0	2	2	0	0	0	2	3	3	0	0	28
11	7	8	5	7	3	6	4	8	3	5	8	3	7	9	3	6	8	9	5	114
12	7	8	10	10	8	0	6	0	5	0	0	4	3	5	0	6	0	3	10	85
13	1	1	0	1	0	0	1	0	1	0	0	1	0	1	0	1	2	0	0	10
14	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	1	3
15	5	3	0	0	1	0	1	1	1	0	1	1	2	2	1	2	2	2	0	25

PPER month 3,last 10 days treatment group questionnaire scores.

Treatment group	1	2	3	**** 4	5	6	7	8	9	10	11	Questionnaire number 12	13	14	15	**** 16	17	18	19	Row sum
16	3	1	0	1	0	0	1	2	0	3	0	0	0	0	0	0	0	5	4	20
17	4	4	0	0	3	3	0	0	5	0	0	8	1	8	0	8	5	5	0	54
18	6	6	10	3	3	3	7	3	0	0	0	3	2	5	0	3	0	5	0	59
19	4	0	0	0	0	3	3	0	0	0	0	0	2	0	3	1	2	0	0	18
20	3	2	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	6
21	0	0	0	0	0	0	3	0	0	0	0	2	0	1	0	1	0	0	0	7
22	3	0	0	0	1	2	1	1	3	3	2	3	3	4	4	4	5	5	5	49
23	3	3	0	0	3	0	6	5	0	0	0	1	0	2	0	1	1	2	2	29
24	1	1	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0	4
25	1	4	0	3	0	0	0	0	0	2	0	0	3	0	0	0	0	0	3	16
26	4	4	0	5	5	1	9	5	3	5	1	3	9	8	0	5	3	7	5	82
27	2	3	0	3	1	0	2	0	0	2	0	1	2	2	0	1	0	2	3	24
28	1	1	0	0	0	1	1	0	0	0	0	0	0	1	0	1	0	0	0	6
29	2	2	0	4	2	0	5	5	0	5	0	3	5	4	1	5	0	3	5	51
30	2	0	2	3	3	1	0	0	5	1	2	4	3	2	2	5	2	3	0	40