THE EFFICACY OF HOMOEOPATHIC SIMILLIMUM IN THE TREATMENT OF PREMENSTRUAL SYNDROME (PMS).

By

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I, Carrie-Ann Laister, do hereby declare that this dissertation represents my own work in both concept and execution.

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DEDICATION

To Alan and Beverley Payne for their endless love, support, guidance and patience.

To Bruce Laister, my husband, for always believing in me and helping me to persevere.

To the rest of my family and friends who have encouraged and supported me. My life has been so blessed by each and every one of you words cannot express how grateful I am.

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ABSTRACT

This study was intended to evaluate the efficacy of homoeopathic simillimum in the treatment of premenstrual syndrome (PMS). The sample group consisted of women between the ages of eighteen and forty, living in the greater Durban area.

PMS is a condition characterized by nervousness, irritability, anxiety, depression, and possibly headaches, oedema, and mastalgia, occurring during the 7 to 10 days before and usually disappearing a few hours after the onset of menses (Beers and Berkow, 1999:1932-1933). 75% of all women suffer from PMS to some degree (Hayman, 1996).

A total of 39 participants with PMS were selected for the study on the basis of inclusion and exclusion criteria (Chapter 3). Participants were randomly divided into 2 groups (treatment and placebo) according to the randomisation sheet. There were 12 withdrawals from the study. 27 of the participants completed the study of which, 14 were on placebo treatment and 13 on active treatment.

The treatment followed the initial consultation, which consisted of 3 powders containing either active ingredient (i.e. simillimum) or matching placebo and a 20ml bottle of liquid containing either active ingredient or placebo. Each participant was required to take one powder daily for three days from day 10 of their menstrual cycle followed by liquid treatment daily till onset of menstruation.

Each participant had 3 consultations with the researcher over a 3 month period; each consultation a month apart. Menstrual Distress Questionnaires (Appendix A) were completed by the participants at each consultation.

The data accumulated via the questionnaires was evaluated using non-parametric tests and analyzed statistically using the Wilcoxon's Signed rank

test and the Kruskal Wallis test. The results were analysed at a 95% confidence rating with $p \leq 0.05$. Data was analysed using the SPSS (version 15.1 ®) for Windows ® statistical software suite.

The intra-group analysis showed statistically significant changes in the subgroups of water retention (p=.020) and appetite changes (p=.010) in the Treatment Group. The Placebo Group showed statistical significant changes in the subgroups of concentration (p=.029), autonomic reaction (p=.013) and appetite changes (p=.035). The inter-group analysis failed to reveal any statistical significance. Therefore, the conclusion is that homoeopathic simillimum was not effective in the treatment of premenstrual syndrome (PMS).

There were clinical improvements noted by participants during the study which suggest that more research into the treatment of PMS should be conducted. Studies with a larger sample group over a longer time frame with daily outcome measures would give a better indication of the efficacy of the homoeopathic simillimum on premenstrual syndrome.

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DEFINITION OF TERMS

SIMILLIMUM

Swayne (2000:194) defines the simillimum as the drug picture most like the clinical picture in the patient. It is arrived at through carefully analysis of information found in the homoeopathic case record.

REMEDY

A means for the cure of a disease or other disorder of body, mind or spirit; any medicine or treatment which promotes restoration of health (O'Reilly, 2001).

PLACEBO

A placebo is made of a medicinally inactive substance used in controlled studies for comparison with presumed active drugs or prescribed with the intent to relieve symptoms or meet a patient's demands i.e. it is a "make believe medicine", and it is allegedly inert and harmless (Beers and Berkow, 1999).

PLACEBO GROUP

Bloch (2002) defines a placebo group as the group of subjects in a clinical trial that receive a non-specific treatment i.e. a placebo. Traditionally this group is used as a measure against which treatment is compared.

TREATMENT GROUP

The group of subjects in a clinical trial who receives treatment that is specific for a given condition (Bloch, 2002).

MENSTRUATION

Bleeding that occurs with the cyclic breakdown and shedding of the uterine mucosa in the absence of pregnancy; it is normally preceded by discharge of an ovum from the ovary and usually occurs approximately every 28 days (from the start of one menstrual period to the start of the next) and lasts three to five days. Also called menses (Dox, *et al*. 2001).

MENARCHE

The first menstrual period (Dox, *et al*. 2001).

PREMENSTRUUM

The period immediately preceding the occurrence of the menstrual flow (Sarawan, 2001).

CHAPTER 1

1.1 INTRODUCTION

For thousands of years – up to and including decades of the present century – very little, if anything, was done to alleviate the unpleasant symptoms which the vast majority of women experience while they are menstruating, nor the whole complex (or syndrome) of problems, mental and physical, which affect far more women than is generally realized during the premenstrual phase of their cycle (Sheeve, 1992:14-15).

Premenstrual syndrome (PMS) is a condition characterized by nervousness, irritability, anxiety, depression, and possibly headaches, oedema, and mastalgia, occurring during the 7 to 10 days before and usually disappearing a few hours after the onset of menses (Beers and Berkow, 1999:1932-1933). There are over 150 symptoms that have been attributed to PMS (Lichten, 2005). PMS was first identified as a true medical disorder by Dr Robert T Frank in 1931 in his paper called “Hormonal Causes of Premenstrual Tension” (Dixie Health, 2006).

According to some studies, 75% of all women suffer from PMS to some degree (Hayman, 1996). Of the estimated 40 million sufferers, more than 5 million require medical treatment for marked mood and behavioural changes (Litchen, 2000). Approximately 2% to 5% of women have severe PMS but many have only mild or moderate symptoms. PMS is most common in women in their 20’s and 30’s, and ceases entirely at menopause (as cited by Sarawan, 2001).

In a study conducted to assess the impact of premenstrual symptomatology on functional and treatment-seeking behaviour for a community-based sample of women in the United States, United Kingdom and France it was found that functional impairment tended to be highest at home, followed by social,

school, and occupational situations. Among working women, over 50% reported their occupational functioning being at least somewhat affected. Of women who ever missed work because of symptoms, 1-7 days were missed in the past year. Almost three fourths of the women had never sought treatment, and symptom severity was an important factor in treatment-seeking behaviour (Hylan, *et al.* 1999).

A study conducted in a UK women's prison showed that half the inmate's offences had been committed in the paramenstruum time (four days prior to the start of the menstruation and first four days of menstruation) (Hayman, 1996).

Homoeopathy, based on the 'law of similars' is a system of medical therapeutics that subscribes to fundamental laws of nature. This allows homoeopathic remedies to utilise and enhance the body's curative powers. Homoeopathy is a curative system of medicine as it restores the patient to health and balance, both mentally and physically (Eizayaga, 1991: 11, 37). The simillimum is the medical potency capable of producing a set of symptoms which are the most similar to those in the case of disease to be cured (O'Reilly, 2001).

Homoeopathy is considerably cheaper than conventional medicine, making it a desirable alternative to allopathic medication (Ullman, 1991: 49). Homoeopathic treatments have no harmful side effects and are safe to treat during pregnancy, menopause and for babies to take. The remedies work gently to stimulate the body's own natural defences with results that may be powerful and long lasting (Traub, 2006). Menstrual disorders at all ages and stages can be treated effectively with homoeopathy (Bloch and Lewis, 2003).

1.2 PROBLEM STATEMENT

The purpose of this double-blind placebo controlled study was to evaluate the efficacy of homoeopathic simillimum in the treatment of Premenstrual

syndrome in terms of patient's perception of the treatment using the Moos Menstrual Distress Questionnaire (Moos, 1968) (*Appendix A).*

1.3 ASSUMPTIONS

- **Participants took the medication as prescribed.**
- **Participants were truthful in answering questionnaires.**

1.4 HYPOTHESES

It is hypothesised that simillimum will have a significant impact on premenstrual syndrome in terms of the findings of the Menstrual Distress Questionnaire.

It is hypothesised that simillimum will have a more significant impact on premenstrual syndrome compared to placebo in terms of the measurement tool completed during the study.

For the above two hypotheses, the null hypothesis states that there is no significant difference between the relevant variables. The alternate hypothesis states that there will be significant difference between the variables according to the measurement tool.

CHAPTER 2

2.1. INTRODUCTION

Premenstrual ailments are some of the most common disorders suffered by women today. It has been shown that women can have radical behavioural, emotional and physical reactions to the hormonal changes occurring in the premenstruum that can impact all aspects of their lives (Hayman, 1998). Although extensive research is still being done, medical science has not yet come up with the perfect solution (Kirtland, 1995).

Premenstrual syndrome (PMS) is a recurrent luteal phase condition characterized by physical, psychological, and behavioural changes of sufficient severity to result in deterioration of interpersonal relationships and normal activity (Moreno, 2006). Up to 80% of women experience mood and physical symptoms associated with menstrual cycle. Commonly reported symptoms are irritability, anger, fatigue, physical swelling or bloating and weight gain (Hylan, *et al.* 1999).

More than fifty years ago premenstrual tension was methodically investigated and described by Dr. Robert T. Frank of New York, although, at the time he referred to Premenstrual Syndrome as “premenstrual tension". PMS is now recognized the world over as being a widespread problem. In 1931 Dr. Frank read his history making paper, "Hormonal Causes of Premenstrual Tension" at a meeting of the New York Academy of Medicine.Scientists who were investigating problems associated with menstruation were struck by the constant appearance of what they labelled premenstrual tension (PMT). PMT was their umbrella term for depression, extreme fatigue, and irritability. However as research continued, it became clear that the "tension" evident during the premenstrual time was only part of what had to be called a syndrome. There were just too many other symptoms that constantly occurred prior to menstruation. Important findings about the distressing symptoms of PMS, and in fact, the term Premenstrual Syndrome came from the efforts of two English physicians,

Dalton and Greene. In 1953 they published "The Premenstrual Syndrome", which was the first PMS paper in medical literature in the British Medical Journal. (Dixie Health, 2006).

Dalton describes the Premenstrual Syndrome as the most prevalent of endocrine disorders. The endocrine system consists of glands that secrete substances into the blood. These substances have an action on a specific organ. In her book, "The Premenstrual Syndrome", she says this title covers a wide variety of cyclical symptoms which regularly recur at the same phase of each menstrual cycle. The most common time for repeated symptoms is during the premenstruum or early menstruation, but occasionally symptoms occur at ovulation. She says that the onset of the full menstrual flow usually brings dramatic and complete relief, but as there may be slight menstrual loss for a day or two before the onset of full menstruation it is not uncommon to find symptoms continuing through the first day or two of each cycle (Dixie Health, 2006).

Symptoms of PMS have been reported to affect as many as 80% of women of reproductive age some time during their lives. Recent studies indicate that 14-88% of adolescent girls have moderate-to-severe symptoms. Another 3-5% of women meet the criteria for Premenstrual Dysphoric Disorder (PMDD). PMS affects women with ovulatory cycles. Older adolescents tend to have more severe symptoms than younger adolescents. Women in their fourth decade of life tend to be affected most severely. PMS resolves completely at menopause (Moreno, 2006).

Singh, Berman, Simpron and Annechild (1998) found that women were more frequently aware of symptoms related to PMS rather than a recognition of a formalised medical syndrome. Less than half the women reporting symptoms had taken either over-the counter or prescription drugs. Women who tried complementary therapies generally found them to be effective.

2.2. IMPACT OF PMS

A study conducted in the USA surveyed 1052 women (aged 21-64) telephonically to find out the respondent demographics, respondent knowledge of PMS, the incidence rate of common symptoms and remedies being used to control symptoms. This study concluded that 41% of the women indicated that they suffered from PMS, and an additional 17% indicated that they experienced symptoms prior to their menstrual cycle commonly associated with PMS, including pain, bloating, feeling more emotional, weight gain and food cravings, although they did not associate these symptoms explicitly with PMS. Of those women reporting PMS symptoms, about 42% took either prescription or over-the-counter medications for relief of symptoms. The conclusions drawn from the study were that women are more frequently aware of symptoms related to PMS rather than a recognition of a formalised medical syndrome. Women who tried complementary therapies generally found them to be effective (Singh *et al.*, 1998).

2.2.1. Economic impact

Dean and Borenstein (2004) conducted a study to investigate the relationship between work productivity and impairment due to Premenstrual Syndrome. They took a sample group of women aged between 18 to 45 years of age who, for two consecutive menstrual cycles, completed a “daily rating of severity of problems” form to record daily symptoms. In the workplace, women with PMS reported higher absenteeism rates (2.5 days vs. 1.3 days) and more workdays with 50% or less typical productivity per month (7.2 days vs. 4.2 days). Women with PMS in one of two menstrual cycles reported a greater number of days with impairment in routine work, school, and household activities in comparison with women without PMS. The results indicated that PMS leads to substantial decrease in normal daily activities and occupational productivity and significantly increased work absenteeism.

Hylan, Sundell and Judge (1999) conducted a study to assess the impact of premenstrual symptomatology on functional and treatment-seeking behaviour for a community-based sample of women in the United States, United Kingdom and France. A sample of 1045 menstruating women (aged 18-49) completed a telephonic questionnaire that measured, at a point in time, premenstrual symptoms, impact on functioning, and treatment-seeking behaviour. Results were generally consistent across the three countries. Irritability / anger, fatigue, and physical swelling / bloating, or weight gain were among the most commonly reported symptoms (approximately 80%). Functional impairment tended to be highest at home, followed by social, school and occupational situations. Among working women, over 50% reported at least somewhat affected occupational functioning. Of women who ever missed work because of symptoms, 1-7 days were missed in the past year. Almost three quarters of the women had never sought treatment, and symptom or symptoms' severity was an important factor in treatment-seeking behaviour.

2.2.2. Social impact

A UK Medical Committee conducted a study on women involved in car accidents and found that 48% of these accidents occur during the premenstruum. The expected result would have been for 25% of accidents to occur as premenstruum accounts for one in four weeks. Another study revealed that accidents are far more common during the premenstruum than at any other time, based on increased hospital administrations and visits to doctors' surgeries. These findings indicated how in the premenstruum a woman is far more accident prone and so can be more hazardous to have in the work place (Sheeve, 1992).

A study conducted in a UK women's prison showed that half the inmate's offences had been committed in the premenstruum time – the three or four days before a period begins, when the symptoms of PMS would be at their peak

(Hayman, 1996). Cases have been heard in the courts of women who temporarily “lose their minds” during the premenstruum due to PMS and they have received lighter sentences. One case in point was Mrs. Christine English who had no criminal record but in a fit of rage drove her car over her lover and killed him. Her intention was not to kill him she stated that she ‘just snapped’ and jammed her foot on the accelerator, intending to bump into him and hurt him and shut him up. The courts accepted her claim and she was given a conditional discharge for twelve months and banned from driving for the same period (Sheeve, 1992).

2.3. TYPES OF PMS

The most common symptoms which women with PMS complain about can be divided into 5 subgroups:

Category	**Symptoms**
PMS-A, anxiety	Difficulty sleeping, tense feelings, irritability, clumsiness, mood swings
PMS-C, craving	Headache, cravings for sweet foods, cravings for salty foods, cravings for other types of food
PMS-D, depression	Depression, angry feelings for no reason, feelings that are easily upset, poor concentration or memory, feelings of low self-worth, violent feelings
PMS-H, hydration	Weight gain, abdominal bloating, breast tenderness, swelling of extremities
PMS-O, other	Dysmenorrhea, change in bowel habits, frequent urination, hot flushes or cold sweats, general aches or pains, nausea, acne, allergic reactions, upper respiratory infections

(Moreno, 2006)

2.3.1. Type A

This type of PMS is characterised by anxiety: irritability, crying without reason, verbal and sometimes physical abuse, feeling “out of control”, or Dr. Jekyl-Mr Hyde behaviour changes (Lichten, 2001). This type of PMS is the most common subtype affecting 65-75% of PMS sufferers (Lockie and Geddes, 1992:67). In some women the anxiety is followed by depression. The symptoms get worse in the days before the menstrual period and are relieved by its onset. The cause of type A is most likely due to excessive levels of oestrogen and inadequate levels of progesterone circulating in the body (Lark, 1984:27); however there is no scientific evidence to confirm this theory (Sheeve, 1992).

2.3.2. Type C

This subtype is characterised by cravings: food cravings, usually for sweets or chocolates; dairy products including cheese, and on occasion, alcohol or food in general (Lichten, 2001). This subtype also includes symptoms like headaches, fatigue and palpitations. This affects 24-35% of premenstrual women (Lockie and Geddes, 1992:67). Many women with PMS note an increased craving for refined carbohydrates especially sugar, chocolate and pastries, and eat larger quantities of these foods before their period than they normally would. This craving is made worse by stress. A few hours after indulging in these foods, many women experience fatigue, headaches, shaking and dizziness (Lark, 1984:29).

2.3.3. Type D

Type D is characterised by depression: confusion, clumsiness, forgetfulness, withdrawal, fearfulness, paranoia, suicidal thoughts and rarely, suicidal actions (Lichten, 2001). This affects 23-35% of women and is more commonly found in combination with PMS type A. The PMS type A occurs first and is followed by type D symptoms a few days before the onset of the period (Lockie and Geddes,

1992:67). In these women oestrogen levels are found to be abnormally low, and the depressant effects of high or normal progesterone are not counterbalanced by oestrogen (Lark, 1984:30).

2.3.4. Type H

Women with type H complain of heaviness or headaches: fluid retention leading to headaches, breast tenderness, abdominal bloating and weight gain (Lichten, 2001). This affects 65-72% of sufferers (Lockie and Geddes, 1992:67). These women tend to retain excess salt and fluid, caused by an excess production of the pituitary hormone adreno-corticotrophic hormone (ACTH). The ACTH is then circulated via the blood to the adrenal glands (Lark, 1984:30). Aldosterone release causes the kidneys to retain water and salt so less urine is excreted (Lockie and Geddes, 1992:67).

2.3.5. Type O

This subgroup is for all the other symptoms not accounted for in the first 4 subgroups. Women with type O complain of dysmenorrhoea, change in bowel habits, frequent urination, hot flashes or cold sweats, general aches or pains, nausea, acne, allergic reactions, upper respiratory infections (Moreno, 2006).

The above shows exactly how multifaceted PMS is, with five different problem entities often coexisting in the same women (Lark, 1984:30).

2.4. SIGNS AND SYMPTOMS

Most women experience some symptoms which are related to the menstrual cycle. In many, women the symptoms are not disabling and are of short duration, while others may experience a broad range of symptoms that disturb normal ability to function (Hayman, 1996).

PMS is a condition characterized by nervousness, irritability, anxiety, depression, and possibly headaches, oedema, and mastalgia, occurring during the 7 to 10 days before, and usually disappearing a few hours after, the onset of menses. Symptoms last for a few hours up to 10 days before a period and usually stop when the flow begins. The most common complaints are changes in mood and psychological changes – irritability, nervousness, lack of control, agitation, anger, insomnia, difficulty in concentrating, lethargy, depression, and severe fatigue. There are also physical symptoms during this premenstruum time – oedema, transient weight gain, oliguria, breast fullness and pain, headaches, vertigo, syncope, paraesthesia of extremities, easy bruising, cardiac palpitations, constipation, nausea, vomiting, changes in appetite, pelvic pressure or heaviness, backache and acne (Beers and Berkow, 1999:1932-1933).

The most common symptoms are:

- Headache
- Swelling of ankles, feet, and hands
- Backache
- Abdominal cramps or heaviness
- Abdominal pain
- Abdominal fullness, feeling gaseous
- Muscle spasms
- Breast tenderness
- Weight gain
- Recurrent cold sores
- Acne aggravations
- Nausea
- Bloating
- Constipation or diarrhoea
- Decreased coordination
- Food cravings

- Less tolerance for noises and light
- Anxiety or panic
- Confusion
- Difficulty concentrating
- Forgetfulness
- Poor judgement
- Depression
- Irritability, hostility or aggressive behaviour
- Increased guilt feelings
- Fatigue
- Slow, sluggish, lethargic movement
- Decreased self-image
- Sex drive change, loss of sex drive
- Paranoia or increased fears
- Low self-esteem

(Thompson, 2004)

2.5. POSSIBLE AETIOLOGY

For many years, PMS was dismissed as a psychological problem. We now know that this is a physiological problem and not purely a psychological one. However it is still far from clear what causes all the symptoms. It is possible that there is more than one cause of PMS and that there may be different causes of symptoms in different people. One of the reasons for PMS may be hormonal imbalance – excessive levels of oestrogen and inadequate levels of progesterone – as well as sensitivity to fluctuating hormones. Diet may be an important contributing factor for some women. Unstable blood sugar levels are an important factor as well. PMS has also been linked to food allergies, changes in carbohydrate metabolism, hypoglycaemia, and malabsorption. Other suspected causes of PMS symptoms include erratic levels of beta-endorphins (a

narcotic like substance produced by the body). All these play a part in PMS. (Balch and Balch, 2003).

2.5.1. Hormonal imbalance

2.5.1.1. Oestrogen and progesterone imbalance

PMS occurs when there is oestrogen dominance. Depression, loss of sex drive, sweet cravings, heavy periods, weight gain, breast swelling and water retention can all be attributed to oestrogen dominance. Oestrogen dominance can be due to excessive exposure to oestrogenic substances, or a lack of progesterone, or a combination of both (Holford, 2004: 27-8). The variation of oestrogen and progesterone levels coincides with the onset and relief of PMS. However the evidence is inconsistent and is still inconclusive (Hayman, 1996).

2.5.1.2. Prolactin

Some studies have shown that there is an increase in prolactin during the luteal phase. Halbreich found that women with PMS had higher prolactin levels than women who did not have PMS symptoms. Prolactin is produced in the pituitary gland and its function is to stimulate the development and growth of breast tissue. If the pituitary produces too much prolactin this will lead to breast tenderness, lumpiness and enlargement, and it may also alter the amount or balance of oestrogen and progesterone produced in the body, and affect mood (Hayman, 1996).

2.5.1.3. Prostaglandins

A diet-related explanation concerns the role of prostaglandins in PMS. These are essential fatty acids that are made by the body and which are nutritionally important for growth and health. The most important of these is linoleic acid, a polyunsaturated fatty acid found in cereals, legumes and vegetables. If most of the fat in a woman's diet is obtained from animal fat she may have a diet that is low in linoleic acid. Prostaglandins are responsible for inflammation and pain in

response to tissue damage. They also have a regulating effect on hormones such as oestrogen, progesterone and prolactin. A deficiency in prostaglandins may lead to the imbalance in hormones that causes PMS symptoms. The dietary deficiency of essential fatty acids which leads to a deficiency in prostaglandins would cause PMS. Some studies have indicated that prostaglandins increase during the luteal phase and decline during menstruation as a normal and natural part of the menstrual cycle (Hayman, 1996).

2.5.1.4. Opiods

One argument is that PMS is linked to opium-like substances which are produced in the brain (endogenous opiod peptides or endorphins). These are produced to control body temperature, bowel function and whether one feels tired, hungry, happy or sad. PMS symptoms mimic the symptoms of narcotic withdrawal e.g. nausea, cramps and depression. (Studies show that these opiods are not only produced by the brain but some are also affected by chemicals produced by the ovaries, so the levels may change throughout the menstrual cycle.) If, in common with other ovarian hormones, the levels are low in the premenstruum, this may account for the drop in mood. Further studies are needed to substantiate this theory (Hayman, 1996).

2.5.2. Nutritional

2.5.2.1. Blood sugar

Another theory is that PMS is related to low blood glucose. Glucose is the body's chief source of energy and is carried by the blood to all tissues. If one did not eat for a long period, there would be a decrease in blood glucose levels. However, usually the level is kept within fairly narrow limits by the action of various hormones such as insulin, glucagon and adrenaline. Glucose can be stored in the liver and muscles so that if these levels begin to drop these reserves can be released. However the release of adrenaline to stimulate this effect has the side effect of causing stress symptoms, making one tired and jittery. People have

been noted to experience sweet cravings boost energy levels by eating chocolates and sweets, which can actually make the situation worse. There is a quick increase in blood glucose levels followed by an immediate “rebound” reaction where the levels fall. The decrease in blood glucose causes the release of more adrenaline which has a positive feedback effect aggravating the situation. Adrenaline releases glucose from the cells causing water uptake, which causes the bloating experienced by PMS sufferers (Hayman, 1996).

2.5.2.2. Dietary deficiencies

Another diet-related argument is that PMS is linked to vitamin and mineral deficiencies. The symptoms of various dietary deficiencies can be shown to be similar to those of PMS, most notably a lack of vitamin B6, E, zinc and magnesium, and others. Modern diets are frequently lacking in these essential dietary factors (Hayman, 1996). In the premenstruum, women often have cravings for the B vitamins, which is similar to a craving for sugar. Instead of ingesting the vitamins, sugar is eaten such as cakes and chocolates and the craving is satisfied. These cravings should be dealt with by taking vitamins rather than sugars (Sandler, 1991).

The deficiency of the essential fatty acids (EFAs) has come to light in recent years as a likely cause of PMS as EFAs are essential to the production and regulation of hormones. The deficiency of EFAs leads to the hormonal imbalance that results in premenstrual symptoms. The efficacy of Vitamin B6 (pyridoxine) in the treatment of premenstrual syndrome has been attributed to its role in metabolising EFA rather than a direct action on the hormones (Sheeve, 1992).

Calcium supplementation has been shown to reduce many symptoms of PMS by as much as 30%. The deduction from this is that calcium deficiency is a cause of PMS (Balch and Balch, 2003). Magnesium deficiency has been linked with breast pain, water retention, cravings, tension headaches, depression and anxiety (truestarhealth.com).

2.6. DIAGNOSTIC CRITERIA

According to Dalton (1984) the diagnostic criteria for premenstrual syndrome are:

- Symptoms must occur exclusively during the second half of the menstrual cycle.
- Symptoms increase in severity as the cycle progresses.
- Symptoms must be relieved by the onset of full menstrual flow.
- There must be an absence of symptoms in the postmenstruum.
- Symptoms have to be present for at least 2 consecutive cycles.

2.7. OUTCOME ASSESSMENT TOOL

The Moos Menstrual Distress Questionnaire (MDQ) (Moos, 1968) (Appendix A) is one of the methods of assessing premenstrual symptomatology. Other methods include the Premenstrual Assessment form and the Daily Menstrual Charts. There are 45 symptoms in the MDQ and these are divided into nine sub-scales. These sub-scales are: pain, water retention, control, negative affect, autonomic reaction, concentration, behavioural changes, appetite changes and arousal. The subjects are asked to assign numerical weight according to their experience of each of the 45 symptoms (Hawes, 1992). The MDQ was the main assessment tool used in this study.

The Moos Menstrual Distress Questionnaire (MDQ) was selected for this trial due to its usage in all previous PMS research seen by the researcher.

In a study to test the efficacy of the MDQ it was concluded that the Moos factors effectively represent the structure of the menstrual cycle symptoms. The aim of the study was to determine whether Moos' factors could be replicated based on daily and prospective completion of the MDQ in women who were unaware of the study's aims. One hundred and eighty-seven women from the general community

(mean age 30 years) completed a modified version of the MDQ daily for 70 days. Principle components analysis of the modified MDQ items during the follicular, late luteal and menstrual phase indicated that a six-factor solution similar to that derived by Moos, best summarised the data. A number of symptoms, however, loaded highly on more than one factor. This created some instability in the solution and may explain the discrepancies in previous research (Ross, *et al.* 2003).

A study published in the British Journal of Psychiatry found the Moos MDQ to be a useful method for assessing menstrual distress. Nineteen volunteers completed a MDQ daily for a period exceeding one menstrual cycle. The data were analysed, using a least mean square method of fitting sine waves. The fact that the results obtained on this group are essentially those found by other researchers looking at the menstrual cycle suggests that this may be a useful method of assessing menstrual distress (Sampson and Jenner, 1977*)*.

An assessment of the Moos MDQ was done by the American Psychosomatic Society which found the MDQ to be consistent and highly reliable in reporting symptoms of the menstrual cycle. The MDQ was analysed for split-half and test-retest reliability. The experimental group was given neutral instructions to determine if the knowledge of the purpose of the questionnaire would affect the symptom rating. The results indicated that the MDQ is internally consistent and does have high test-retest reliability (Markum, 1976).

2.8. DIFFERENTIAL DIAGNOSIS

2.8.1. Cyclic Pelvic Pain

2.8.1.1. Premenstrual Dysphoric Disorder

Premenstrual Dysphoric Disorder (PMDD) is a condition associated with severe emotional and physical problems that are linked closely to the menstrual cycle. Symptoms occur regularly in the second half of the cycle and end when menstruation begins or shortly thereafter. PMDD is not just a new name for premenstrual syndrome (PMS), a condition that affects as many as 75% of menstruating women. It is, considered to be a very severe form of PMS that affects about 5% of menstruating women. Both PMDD and PMS share symptoms in common that include depression, anxiety, tension, irritability and moodiness. Women with PMDD experience severe PMS that disrupts their everyday lives to the point that they can no longer function effectively (Madison Institute).

2.8.1.2. Dysmenorrhoea

Dysmenorrhoea is a painful menstrual period (Dox *et al.,* 1993). This can be classified into congestive or spasmodic dysmenorrhoea. Spasmodic dysmenorrhoea is not part of PMS. It is related to the uterine contractions which cause shedding of the endometrial lining. The pain is due to the interruption of the normal blood flow to the muscle fibres caused by to the strong sustained contraction of the muscle which results in an accumulation of chemical metabolites in the muscle causing pain. Spasmodic dysmenorrhoea occurs most often in young women and girls in the time following menarche, before the uterine muscles have received sufficient oestrogen to complete their development. The pain experienced with spasmodic dysmenorrhoea is spasmodic and occurs in the lower abdomen and small of the back and is a heavy, bloated, dragging feeling sometimes accompanied by dull or shooting pain in the genital area. This is not a premenstrual symptom as it occurs during the period. However it can occur in a person with PMS and so the distinction

between PMS and Dysmenorrhoea for the patient is difficult to distinguish. Congestive dysmenorrhoea is not true dysmenorrhoea as it occurs before the onset of menses. It is due to the congestion of blood in the vessels in the pelvis. The pain is in the pelvic and genital regions and is a dull persistent pain in contrast to period pain which is cramp-like. Congestive dysmenorrhoea is a symptom of PMS (Sheeve, 1992).

2.8.1.3. Mittelshmertz Phenomenon

Mittelshmertz Phenomenon refers to a frequently occurring unilateral lower abdominal pain that occurs mid-cycle due to ovulation. Rupture of the follicle and subsequent irritation of the peritoneum may produce pain. The pain, although sometimes severe, resolves spontaneously (Beers and Berkow, 1999).

2.8.1.4. Endometriosis

Endometriosis is an abnormal condition in which the uterine mucous membrane invades other tissues in the pelvic cavity (Dox *et al.,* 1993). The cyclical engorgement of this ectopic endometrial tissue results in pain, bleeding, diarrhoea, constipation and lower back pain. The onset of endometriosis is usually in females between the ages of 20-45 (Haslett, *et al.* 2002). In the early stages of endometriosis pain is caused which starts several days before the menses and continues through the first few days. This disorder becomes chronic and pain commonly occurs at various times unrelated to the menstrual period (Beers and Berkow, 1999).

2.8.2. Affective disorders/ Mood disorders

2.8.2.1. Depression

Symptoms of major depression include feelings of sadness, loss of interest in normally pleasurable activities, changes in appetite and sleep, loss of energy,

and problems with concentration and decision-making. Women are twice as likely as men to experience major depression. Depression can also cause a wide variety of physical complaints, such as gastrointestinal problems (indigestion, constipation or diarrhoea), headache and backache. Many people with depression also have symptoms of anxiety (International Society for Affective Disorders, 2006).

2.8.2.2. Seasonal Affective Disorder

Seasonal Affective Disorder (SAD) is a pattern of depression related to changes in seasons and a lack of exposure to sunlight. It may cause headaches, irritability and a low energy level (Mayo Clinic, 2006).

2.8.2.3. Dysthmia

Dysthmia is a chronic depression of mood which does not currently fulfil the criteria for recurrent depressive disorder in terms of either severity or duration of individual episodes. The balance between individual phases of mild depression and intervening periods of comparative normality is very variable. Sufferers usually have periods of days or weeks when they describe themselves as well, but most of the time they feel tired and depressed; everything is an effort and nothing is enjoyable. They brood and complain, sleep badly and feel inadequate, but are usually able to cope with the basic demands of everyday life (World Health Organisation, 2007).

2.8.2.4. Adjustment Disorder

Adjustment Disorder is when the response to a stressful or traumatic event is signs and symptoms of depression or anxiety. The disorder can be acute (lasting less than six months) or chronic. An adjustment disorder can develop following a single stressful event or as result of an accumulation of stress. The behavioural

changes found in Adjustment Disorder are not restricted to the premenstruum but the behaviour could be misdiagnosed as PMS (Mayo Clinic, 2006).

2.8.3. Other conditions

2.8.3.1. Peri-menopause

It may be difficult to distinguish peri-menopause from PMS in certain instances. If one is over 40, symptoms such as joint pain, depression, anxiety, forgetfulness, increased urge to pass urine and cystitis may actually be caused by the climacteric (Hayman, 1996:65). In addition one should consider the possibility of premature menopause in those women who are under the age of 40 (Beers and Berkow, 1999).

2.8.3.2. Chronic Pelvic Inflammatory Disease (PID)

PID is widespread infection in the reproductive and pelvic organs. When chronic, there may be discharge, pain and general ill health (Beer and Berkow, 1999). PID may become worse before a period begins (Hayman, 1996:66).

2.8.3.3. Hypothyroidism

The signs and symptoms of hypothyroidism vary widely, depending on the severity of the hormone deficiency. In general, problems tend to develop slowly, often over a number of years. At first there are symptoms such as fatigue and sluggishness. The metabolism continues to slow; more obvious signs and symptoms of hypothyroidism develop, including: increased sensitivity to cold; constipation; pale, dry skin; a puffy face; hoarse voice; an elevated blood cholesterol level; unexplained weight gain; muscle aches, tenderness and stiffness; pain, stiffness or swelling in the joints; muscle weakness; heavier than normal menstrual periods and depression. Forgetfulness and slowing of comprehension are additional symptoms of hypothyroidism (Mayo Clinic, 2006).

2.9. TREATMENT OPTIONS

2.9.1. Non-pharmacologic Therapy

The most extreme form of treatment for PMS is a hysterectomy with a bilateral oophorectomy. This is only considered in cases of severe PMS where the women has had children and does not wish to have any more. This option is not viable to young girls or women due to the finality of the surgery in relation to being able to have children (Moreno, 2006).

Lifestyle changes can play a big part in curbing symptoms of PMS. Eating properly and getting adequate exercise and rest are the simplest steps to help relieve PMS. Reducing the intake of sodium during the premenstruum will help reduce water retention. Avoiding caffeine assists as caffeine has been linked to symptoms of breast tenderness and anxiety. The intake of caffeine also contributes to the depletion of important nutrients due to its diuretic action. Women who exercise regularly have been shown to have less PMS symptoms than women who don't so getting regular exercise is a good way to control PMS (Balch and Balch, 2003).

Yoga has been found to help in the control of PMS for three reasons. Firstly the postures and breathing technique are designed to instil a peaceful and tranquil state which will calm the physical and mental tension associated with PMS. It decreases tension in the body and so decreases muscular and joint aches and pains. Yoga teaches the maintenance of an upright and balanced posture which relieves fatigue, lethargy and lower back pain. Thirdly some of the yoga postures have been attributed to directly helping with congestive dysmenorrhoea (Sheeve, 1992).

A placebo controlled study was conducted to test the effectiveness of acupuncture to treat Premenstrual Syndrome. The participants were classified as

having severe symptoms and some were on medication (progestin and fluoxetine). The treatment group showed a 77.8% improvement of symptoms in comparison to the 5.9% improvement found in the placebo group. The positive result was attributed to the serotonin and opiod releasing effects of the acupuncture treatment (Habek, *et al*. 2002).

A randomised clinical trial was conducted to determine the efficacy of chiropractic therapy on PMS. In this trial 54 subjects diagnosed with PMS (using the Moos PMS questionnaire plus daily symptom monitoring) and 30 subjects with no diagnosable PMS were recruited. The PMS group had a higher positive response for each of 12 measured spinal dysfunction indexes except for range of motion of the lower back. The indexes where the increases were statistically significant ($P<.05$) were cervical, thoracic, and lower back tenderness, lower back orthopaedic testing, lower back muscle weakness, and the neck disability index. An average of 5.4 of the 12 indexes were positive for the PMS group compared with 3.0 for the non-PMS group. This study proved that there is a relatively high incidence of spinal dysfunction in PMS sufferers compared with a comparable group of non-PMS sufferers. This research suggests spinal dysfunctions as a possible aetiological factor for PMS and that chiropractic manipulation may offer a good alternative approach to treating PMS (Polus and Walsh, 1999).

A study was conducted to see the effect of consuming soy isoflavone on the behavioural, somatic and affective symptoms in women with PMS. The study used 23 women with diagnosed PMS and took place over a seven menstrual cycle time frame. It was a double-blind placebo-controlled, crossover intervention study. The study proved that isolated soya protein containing soy isoflavones may reduce specific premenstrual symptoms but on the totality of the premenstrual symptoms there proved to be insignificant difference between the placebo and active groups (Bryant, *et al.* 2005).

A systemic review was done on 27 randomised controlled trials conducted to show the efficacy of various complementary therapies in the treatment of PMS. (7 Herbal trials, 13 dietary supplement trials and 1 trial of each of the following disciplines: homoeopathy, biofeedback, chiropractic, massage, reflexology, relaxation.) This review showed that despite positive findings in some of the trials reviewed there is very little evidence to prove that complementary medicines are effective for the treatment of PMS (Ernst and Stevinson, 2001). The trials that were reviewed all had a small sample size. The good clinical findings would be more indicative of the efficacy of the therapies if conducted in a larger group because a larger sample size yields more statistically significant results than a small sample.

Psychological treatment has also been found to relieve symptoms of PMS. Education of women about PMS and using a diary to monitor symptoms has been noted to help women feel more in control and reduce symptoms. Teaching women how to relax by the use of the relaxation response, biofeedback and guided imagery helps to relieve tension and so help the PMS. Cognitive behavioural therapy has also been clinically noted to help symptoms of PMS (Moreno, 2006).

2.9.2. Dietary Supplementation

Dietary supplements that have been evaluated in women with PMS include vitamins (A,E, and B_6), calcium, magnesium, multivitamin/mineral supplements, and evening primrose oil. Most studies have been small or poorly designed, efficacy needs to be confirmed in large, well-designed clinical trial before evidence-based recommendations can be made (Dickerson *et al.,* 2003).

2.9.3. Pharmacologic Therapy

2.9.3.1. Over the Counter drugs (OTC)

OTC drugs that are useful to relieve symptoms of PMS include drugs containing mild diuretics, analgesics, prostaglandin inhibitors and anti-histamines. Caution must always be used when combining products due to risk of inadequate dosing of some ingredients in the drugs and excessive dosing of others. It is preferential to use a single product when using OTC drugs to negate this issue (Dickerson *et al*., 2003). Herbal preparations and vitamins (discussed in 2.8.2) are included as OTC.

2.9.3.1.1. Herbal treatments for PMS

Dioscorea villosa (Wild Yam) is known historically to treat 'women's complaints'. It has been used to relieve cramps and mood swings. Wild Yam contains the sterol, diosgenin, with progesterone-like effects which is why it has been attributed to relieve symptoms of PMS (Dixie Health, 2006).

Agnus Castus (Chaste tree) has been shown to help re-establish normal balance of oestrogen and progesterone during the menstrual cycle. The action of re-establishing a normal hormonal balance helps women whose PMS is due to underproduction of progesterone or overproduction of oestrogen. It has a calming soothing effect and relieves muscle cramps. Chaste tree needs to be taken for at least four cycles to determine efficacy (Balch and Balch, 2003).

*Angelica sinensis (*Don Quai) is a traditional Chinese medicine and is often referred to as female ginseng. It helps promote normal hormonal balance and is useful for women suffering from premenstrual cramping and pain (Dixie Health, 2006). Don Quai acts as a mild sedative, laxative, diuretic, antispasmodic and pain reliever along with assisting the usage of hormones by the body (Balch and Balch, 2003).

Chamaelirium luteum (False Unicorn Root) is a Native American traditional medicine which is useful in treating amenorrhoea, painful menstruation and other menstrual irregularities (Dixie Health, 2006).

2.9.3.2. Psychotropic agents

Anti-anxiety and anti-depressant drugs are often utilised to treat the emotional symptoms of PMS (Hayman, 1997). Anti-anxiety agents such as Alprazolam (Xanax) and Buspirone (BuSpar) have been effective in helping the anxiety-related symptoms of PMS. The Selective Serotonin Re-Uptake Inhibitors (SSRI), Fluoxetine (Prozac) and Sertraline (Zoloft), are the first-line drugs for severe emotional symptoms. They work best when taken throughout the month. Clomipramine (Anafranil) given for the full cycle or half-cycle has been effective in treatment of emotional symptoms. Nefazodone, an antidepressant that blocks serotonergic and noradrenergic uptake, recently was shown to be effective in relieving symptoms (Moreno, 2006).

2.9.3.3. Diuretics

Many women complain of bloating and cyclical weight gain due to fluid retention. Diuretics help to turn these excess fluids in the body into urine, increasing the frequency and quantity of urine. Side effects of nausea and dizziness are not uncommon. Some research suggests that not only is premenstrual bloating a normal aspect of cyclical change, but that it is not associated with an actual increase in girth. Fluid may shift around the body, and there may be an increase in distension or pressure in the abdomen, but the actual external measurements do not increase. If this is so diuretics would not be an appropriate treatment (Hayman, 1998: 106).

2.9.3.4. Prostaglandin Inhibitors

Non-Steroidal Anti-Inflammatory (NSAIDS) are agents which are useful for managing the general aches, pains, and dysmenorrhoea associated with PMS. Commonly used drugs in the treatment of PMS are Ibuprofen and Mefenamic Acid (Thompson, 2004).

2.9.3.5. Agents used to alter the menstrual cycle

The oral contraceptive pill (OCP) has been used to regulate the menstrual cycle and alleviate the symptoms of PMS. However in a study conducted in the Royal Edinburgh Hospital where 276 women who considered themselves to have PMS were studied, 171 of which were on the OCP, found that women on OCP experienced delayed or more prolonged pattern of perimenstrual negative mood (Bancroft and Rennie, 1993).

2.10. HOMOEOPATHY

2.10.1. Definition

Homoeopathic prescription of medicines is based on the “Law of Similars”. The idea is that ‘like cures like’, that is, any substance which can produce a totality of symptoms in a healthy human being can cure that totality of symptoms in a sick human being. A homoeopathic remedy helps the body to heal itself, by stimulating the body’s own energies or vital force. The remedies initiate the vital force to rid the body of disease, helping the body to return to health (Vithoulkas, 1998).

Menstrual disorders at all ages and stages can be treated effectively with homoeopathy (Bloch, 2003).

2.10.2. Laws and Principles of Homoeopathy

2.10.2.1. Law of Similars

The “Law of Similars” had its inception round the time of Hippocrates. Hahnemann simply incorporated it into a system of medicine i.e. homoeopathy (Brunton, 1989). The Law of Similars refers to a similarity existing between the ‘toxicological’ action of a substance and its therapeutic action. Any pharmacologically active substance administered to a healthy person will cause a set of symptoms characteristic of the substance. All sick people display a set of morbid symptoms which are characteristic of the disease. These morbid symptoms may be defined as being “a change in the patient’s way of feeling or behaving” brought on by his disease. (Symptoms which are characteristic of a disease but are unique to each person.) The cure, evidenced by the disappearance off all the morbid symptoms, may be obtained by prescribing, in weak or infinitesimal dose, the substance whose experimental symptoms in healthy people are most similar to those symptoms displayed by the ill person (Ross, 2000).

2.10.2.2. The Minimum Dose

Hahnemann developed a unique method of dilution because of his theory of minimal dose in accordance with the Arndt Shultz law. He envisioned that in order to bring about cure, the minimal dose required should be administered. In this way, unwanted toxic effects of the drug can be avoided (Kayne, 2003). This correlated to the Arndt Shultz law which states that for every drug, small doses stimulate, moderate doses inhibit and large doses kill. Thus, as the homoeopathic solution becomes more dilute, the drug should be expected to encourage the healing process (Lessell, 1994:110).

2.10.3. Vital Force

The vital force directs all processes of life in the human being. It adapts to environmental influences, creates emotion, causes thought processes and creativity and conducts spiritual inspiration. It acts on the mental, physical and emotional planes to create balance. That part of the vital force responsible for balance during disease is known as the defence mechanism (Vithoulkas, 1987:59).

2.10.4. Simillimum

The simillimum is a single remedy with the drug picture that matches closest to the symptom picture of the patient (Gaier, 1991). The homoeopathic consultation is so comprehensive; to take into account all aspects of the patient to provide a unique symptom picture. These include: character, stress levels, level of exercise, diet, food preferences, family medical history and the effect of general factors. Each patient is unique so the remedy, which is best suited to the individual, is given, thus different remedies are indicated in different patients (Lockie and Geddes, 1995).

2.10.5. Dilution and Potentisation

Hahnemann found that patients symptoms worsened first before getting better when administered with small, dilute doses. To prevent these aggravations he developed a two step method of dilution. He diluted each remedy by succussing it, or shaking it vigorously, and banging it down on a firm surface at each stage of dilution. By vigorously shaking a remedy, he believed the energy of the substance was released. Hahnemann called these new remedies “potentisations” and the term “potency” is used to describe the dilution or strength of a remedy and is determined by how many times the remedy has been succussed and diluted during preparation (Lockie and Geddes, 1995).

There are three standard scales of homoeopathic serial dilution and potency. The centesimal scale (denoted by c, CH or C) involves serial dilution of 1 in 100. The decimal scale (denoted by x or D) requires serial dilution of 1 in 10. The fifty millesimal scale (or LM) requires serial dilutions of 1 in 50 000 using 3CH as a basis, and 100 succussions per dilution, whereas the decimal and centesimal scale employs 10 succussions per dilution. In each scale, the substance is diluted into an ethanol-water mixture. Substances that are not readily diluted in the ethanol-water mix are prepared by trituration up to the 3CH or 6X potencies, which are readily soluble in ethanol-water mixture. Trituration involves prolonged grinding of the substances in lactose powder in a mortar and pestle (Lessell, 1994).

2.11. HOMOEOPATHIC TREATMENT OF PMS

Martinez (1990) conducted a double-blind placebo-controlled trial using Folliculinum in potencies 9C and 15C in 32 participants. A questionnaire was given to all the participants prescribed Folliculinum at their first consultation, to be collected at the subsequent consultation. The duration of the treatment was two to four months. Of all the participants, 88% showed a satisfactory response to the treatment according to the questionnaire. Most of the participants (61%) noted an improvement from the second cycle after having started the treatment. 93% of the participants felt that the treatment had physiological effects while only 7% felt that the effects might be due to the placebo effect. The most marked effect on particular symptoms was on breast swelling, metorrhagia and menstrual irregularities.

Kirtland (1995) conducted a double-blind placebo controlled study involving 31 women from the greater Durban area where she compared the effect of Folliculinum 15CH to placebo. The results were based on a subjective questionnaire filled in by the participants. The test group (16 women) had 89% improvement, 4% unchanged and 7% worsening of the premenstrual symptoms. The placebo group (15 women) had 7% improvement, 4% unchanged and 89%

worsening of premenstrual symptoms. The improvement ascertained during the trial was statistically significant.

A double-blind study of the homoeopathic treatment of Premenstrual Syndrome used a complex, Premenstron®. The complex containing: *Agnus castus* D1, *Chamomilla radix* D3, *Lillium tiginum* D3, *Caulophyllum thalictroides* D4, *Equisetum arvense* D4, *Zincum valerianicum* D4, *Ignatia amara* D6 and *Kali carbonicum* D6 was compared to placebo. Thirty participants were randomly selected and divided into their respective groups. The statistical results were overall 53.3% improvement in the placebo group while 46.7% worsened. In the treatment group 86.7% showed improvement and 12.3 % worsened. The improvement in the treatment group was not significant enough to verify that the complex was effective when analysed statistically and in comparison with the effect of the placebo (Sarawan, 2001). As the study was conducted as part of a mini-dissertation the test sample was small which resulted in there not being statistical significance in the findings. However based on the clinical findings the homoeopathic complex had significant improvement to merit further research.

A study was conducted in Israel to test the efficacy of treating PMS with homoeopathic simillimum using the cluster method to derive the remedy. The simillimum was selected by the subject filling in a questionnaire which related to the keynote symptoms of 5 polychrest remedies commonly used in the treatment of PMS: *Sepia officinalis, Nux vomica, Pulsatilla nigrans, Natrum muriaticum and Lachesis mutans.* The prescription was made based on the cluster of 'yes' answers relating to each remedy. The remedy with the most positive response was considered the simillimum. The subject was then given a single powder (which was either the placebo or the selected simillimum). The subjects were then monitored for 3 months on a once monthly basis to see the effect of their treatment. The study was a double-blind and placebo-controlled in which the results were only correlated at the end of the study. They observed improvements greater than 30% in 90% of participants receiving the active

treatment and in 37.5% receiving placebo (Yakir *et al.,* 2001). The limitation of this study was the restriction of homoeopathic remedies which could be prescribed for PMS. The focus of the study was the efficacy of the method of prescribing rather than the efficacy of a homoeopathic simillimum. Women were excluded if their symptom profile did not correlate with the selected remedies. However, simillimum prescribing is a holistic process taking the symptom profile of the entire person rather than just the premenstrual symptoms.

2.12. PLACEBO EFFECT

A placebo is made of a medicinally inactive substance used in controlled studies for comparison with presumed active drugs or prescribed with the intent to relieve symptoms or meet a patient's demands i.e. it is a "make believe medicine", and it is allegedly inert and harmless. The placebo has shown repeatedly to have effects on patients, involving both improvement and deterioration in functioning. The list of subjective and objective changes due to placebo has been put down to two possible components of the placebo response (Beers and Berkow, 1999:2585-2586).

There are 3 major mechanisms that can explain the placebo effect:

- The Opioid Model: release of endorphins (which are the body's natural pain killers) in response to the placebo stimulus.
- The Conditioning Model: a learned response to medical intervention.
- The Expectancy Model: a consciously mediated response.

Placebo effect can also result from contact with doctors and other health care providers, a diagnosis, or even attention from a professional alleviates anxiety (Hart, 1999:31-32).

Some patients with severe PMS experience significant and sustained improvement with placebo medication, but the majority report only partial or no improvement (Freeman and Rickels, 1999).

2.13. SUMMARY

PMS is a common complaint for women and yet very little research has been conducted on the subject due to its non-life-threatening nature. PMS is however, a condition which does effect most women at some point in their lives. The effect of PMS is debilitating to some women with days absent or decreased productivity being noted in every menstrual cycle. PMS is a chronic syndrome whose effect is experienced on a mental, emotional and physical level. In some severe cases an example of this is radical behavioural changes to the point of suicidal or homicidal states.

The aetiology of PMS is still unknown and only speculation and clinical experiences have revealed ameliorating treatments. There are many lifestyle options which can be considered to help alleviate the symptoms of PMS. There is a potential for homoeopathic treatment to get to the root aetiology of the PMS as homoeopathic simillimum treats a person as a whole and not a singular complaint. Homoeopathy has proven effective in the treatment of other hormone related complaints.

CHAPTER 3: MATERIALS AND METHODS

3.1 PROBLEM STATEMENT

The purpose of this double-blind placebo-controlled study was to evaluate the efficacy of homoeopathic simillimum in the treatment of premenstrual syndrome (PMS) in terms of the participant's perception of the treatment using the Moos Menstrual distress Questionnaire (Moos, 1968) (Appendix A).

3.2 SAMPLE GROUP

All the measures and procedures that were used in the study were approved by the Faculty of Health Sciences Ethics Committee at the Durban University of Technology. 39 participants were recruited and 27 participants completed the study. Participants were selected via convenience sampling and were recruited on the basis of inclusion and exclusion criteria.

3.2.1 Inclusion Criteria

Participants were selected for the study according to the following criteria:

1. Participants had to be between the ages of 18 years to 40 years.
2. Participants had to be female.
3. Participants had to be literate in English.
4. Participants had to be experiencing symptoms 2-14 days before the onset of menstruation.
5. Participants had to fulfil the diagnostic criteria for Premenstrual syndrome (Dalton, 1984).
    a. Symptoms must occur exclusively during the second half of the menstrual cycle.
    b. Symptoms increase in severity as the cycle progresses.
    c. Symptoms must be relieved by the onset of full menstrual flow.

d. There must be an absence of symptoms in the postmenstruum.
e. Symptoms have to be present for at least 2 consecutive cycles.

3.2.2 Exclusion Criteria

Participants were excluded from the study according to the following criteria:

1. Breast-feeding or pregnant women.
2. Women on treatment for premenstrual syndrome.
3. Menopausal or peri-menopausal women.
4. Women who had started or changed oral contraceptive pill in the previous 6 months.

3.3 RECRUITMENT PROCESS

Participants responded to advertisements that were placed on notice boards at the Durban University of Technology as well as a local pamphlet drop (Appendix B and C).

3.4. ETHICAL ISSUES

In this study, homoeopathic simillimum was compared to placebo in its effectiveness in treating premenstrual syndrome. Apart from participants being divided into treatment and placebo groups, there was no difference in procedures between participants.

Before the initial consultation, participants were given a subject information letter (Appendix D) to read. This informed the participant of the implications of being involved in the study and assured them of the strict confidentiality with which all information was maintained. The researcher explained the need for the use of placebo for comparative purposes and that there was a 50%

chance that they may receive placebo treatment. Due to the fact that premenstrual syndrome is not a life threatening complaint participants were not in any serious health risk if they were to receive placebo treatment. All participants were informed that, upon unblinding, if they had received placebo during the trial that they would receive the relevant homoeopathic remedy at the end of the trial without charge.

If participants met the selection criteria and were willing to participate further, they were given an informed consent form (Appendix E) to sign. Participants understood that they were free to withdraw from the study at any time, without having to give a reason for withdrawing and without affecting their future health care. All participants agreed to participate voluntarily in the study.

3.5. RANDOMISATION AND BLINDING

This was a double-blind study. Participants were assigned numbers sequentially as they entered the study. The numbers corresponded to 36 numbers randomly allocated into two groups (by means of drawing from a hat) forming a randomisation sheet (Appendix F) drawn up by the research supervisor. Eighteen participants were selected for each group (Treatment and Placebo groups). During the study, neither the participants nor the researcher were aware of which group the participants belonged to. Dispensing of medication was performed by the assigned laboratory technician at the Homoeopathic Day Clinic, according to the randomisation sheet. The randomisation sheet was revealed to the researcher once all the 27 participants had completed their three consultations. Participants that received placebo were then called to collect their homoeopathic remedies, at no charge.

3.6. TREATMENT

All remedies were prepared according to the German Homoeopathic Pharmacopoeia (GHP) (British Homoeopathic Association, 1991).

All participants received 3 powders and drops (25ml dropper-bottle) each. The treatment received by the placebo group was indistinguishable from the treatment received by the active treatment group.

The powder in both active treatment and placebo, was a lactose powder containing lactose granules which had been triple impregnated at a 1% volume for volume ratio of either the remedy in 96% ethanol (active treatment) or with 96% non-medicated ethanol (placebo). Granules were made in accordance to method 10 of GHP.

The drops were prepared by placing 10 granules, either remedy impregnated granules or the neutral granules, in a 25ml dropper bottle. 18ml of water was added to the granules and the bottle was swirled to dissolve the granules. 2.5ml of 96% ethanol was added to the bottle once the granules had completely dissolved. The bottle was then closed and succussed ten times. The bottle was then labelled with the relevant instructions for the participant. Solutions were made in accordance to method 5a of the GHP.

The laboratory technician at the clinic dispensed the relevant medication according to the randomisation list. Each participant was to take a single powder daily from day 10 of their menstrual cycle for 3 days followed by drops daily till their next menstruation.

3.7. CONSULTATION PROCEDURES

Participants consulted with the researcher 3 times during the study. After the initial consultation, there were 2 follow-up consultations which were after consecutive menstrual cycles and after having treatment. Participants' involvement in the study ended after 3 menstrual cycles (approximately 12 weeks).

3.7.1. First Consultation

1. This began as soon as the subject information letter (Appendix D) was read and the informed consent form (Appendix E) was signed.
2. A full homoeopathic case history was taken and a physical examination was performed.
3. Participants were required to complete the Menstrual Distress Questionnaire (Moos, 1968) (Appendix A), a personal information form (Appendix F), and fill in the diagnostic criteria for premenstrual syndrome (Dalton, 1984) (Appendix G).
4. Participants were sent to the reception area to collect their prescription.
5. The homoeopathic dispenser on duty at the Homoeopathic Day Clinic dispensed the relevant medication to the respective groups according to the randomization sheet drawn up by the supervisor.
6. Treatment consisted of 3 powders and a bottle containing 20ml of liquid remedy which was either simillimum or placebo.
7. Each participant was required to take one powder daily from day 10 of their menstrual cycle for 3 consecutive days followed by drops daily until their next menstruation.
8. Participants were asked to return for the second consultation after or during the menstruation following taking treatment.

3.7.2 Second Consultation

1. This was a follow-up consultation which included checking of the vital signs.
2. The Menstrual Distress Questionnaire (MDQ) was completed in relation to the previous month.
3. The participant was re-evaluated to see the effects of the treatment. No further remedies were given.
4. The participant was asked to return for the third consultation after or during the menstruation following this consultation.

3.7.3. Third Consultation

1. The MDQ was completed in relation to the previous month.
2. The vital signs were examined.
3. Participants were again questioned to see any lasting effects of the treatment.

On completion of the study, participants from the placebo group were telephonically contacted, and invited to collect their medication (i.e. simillimum) which they received free of charge. Various remedies were prescribed during the study.

3.8. DATA COLLECTION

Participants were assessed using the Menstrual Distress Questionnaire (Appendix A).

3.8.1. Measurement Tools

3.8.1.1. Menstrual Distress Questionnaire

The MDQ measures the physiological and psychological changes that might accompany the fluctuations of hormones during the menstrual cycle. It comprises of 45 symptoms which the participant needed to rate according to severity for the week before their menses, the week of menstruation and the rest of the month. The symptoms are rated from 1 (no symptoms present) to 5 (acute or partially disabling symptoms).

3.8.2. Statistical analysis

All the Menstrual Distress Questionnaires (Moos, 1968) were screened and all the symptoms were assigned numerical values, which were entered on spreadsheets. Statistical evaluation of the data was conducted using SPSS (version 15.1) software suite (444 N. Michigan Avenue, Chicago, Illinois, 60611, USA). Due to the size of the sample, non-parametric statistical tests were used.

3.8.2.1. Procedure 1: Friedman Test

(Intra-group Tests for Treatment Group and Placebo Group)

The Friedman Test was conducted based on the result from the MDQ (comparing symptom by symptom). It tested for a significant difference in population means between the Treatment group and Placebo group.

a. Hypothesis testing

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

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

b. Decision rule

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

3.8.2.2. Procedure 2: Wilcoxon's Signed Rank Test
(Intra-group Tests for Treatment Group and Placebo Group)

Wilcoxon's Signed Rank Test was conducted based on the results from the MDQ (comparing symptom by symptom). It tested for a significant difference in population means between readings within the Treatment group and the Placebo group.

a. Hypothesis testing

The null hypothesis H_0, states that there is no significant difference between the three consults being compared at the $\alpha = 0.05$ level of significance. The alternative hypothesis H_1, states that there is a significant difference between the three visits being compared.

b. Decision rule

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

3.8.2.3 Procedure 3: Kruskal-Wallis Test

(Inter-group tests between both Groups)

The inter-group analysis was done using the Kruskal-Wallis Non-parametric Analysis of Variance (ANOVA) method. The Treatment and Placebo groups were compared to each other (using the MDQ) with regards to a comparison of intensity of symptoms and quantity of symptoms.

The two groups were compared to each other with regard to analysis of each group of symptoms (symptom grouping). Inter-group analysis of individual symptoms was also conducted.

a. Hypothesis testing

The null hypothesis H_0 states that there is no significant difference between the three consults being compared at the $\alpha = 0.05$ level of significant. The alternative hypothesis H_1, states that there is a significant difference between the three visits being compared.

b. Decision rule

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

3.8.2.4 Procedure 4: Comparison using bar charts

Analytical findings were summarised in visual form by using means to construct bar charts to compare readings of the Treatment and Placebo groups with respect to scores given for the MDQ. Bar charts were placed after the appropriate tables. Bar charts were also used to explain mean scores at

each consultation for 9 subscales of pain, concentration, behavioural changes, autonomic reactions, water retention, negative affects, arousal, control and appetite changes.

CHAPTER 4

4.1. DEMOGRAPHIC DATA

4.1.1. Age

The study consisted of 27 women between the ages of 18 and 40 years of age. There were 3 participants (11%) between the ages of 18-21 and 11 participants (41%) between the ages of 22-25. 7 participants (26%) were between the ages of 26-30. 3 participants (11%) between the ages of 31-35. 3 participants (11%) were between the ages of 36-40 (see Figure 4.1).

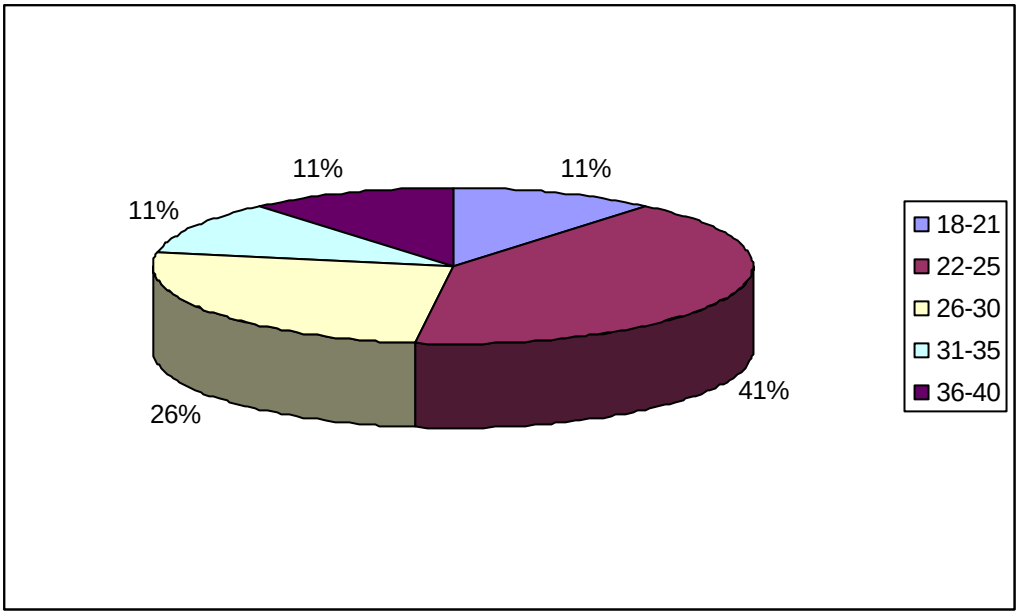

Figure 4.1 Pie Chart: Percentage of Age Groups

4.1.2. Marital Status

There were 8 married participants (30%) and 19 single participants (70%) (See Figure 4.2).

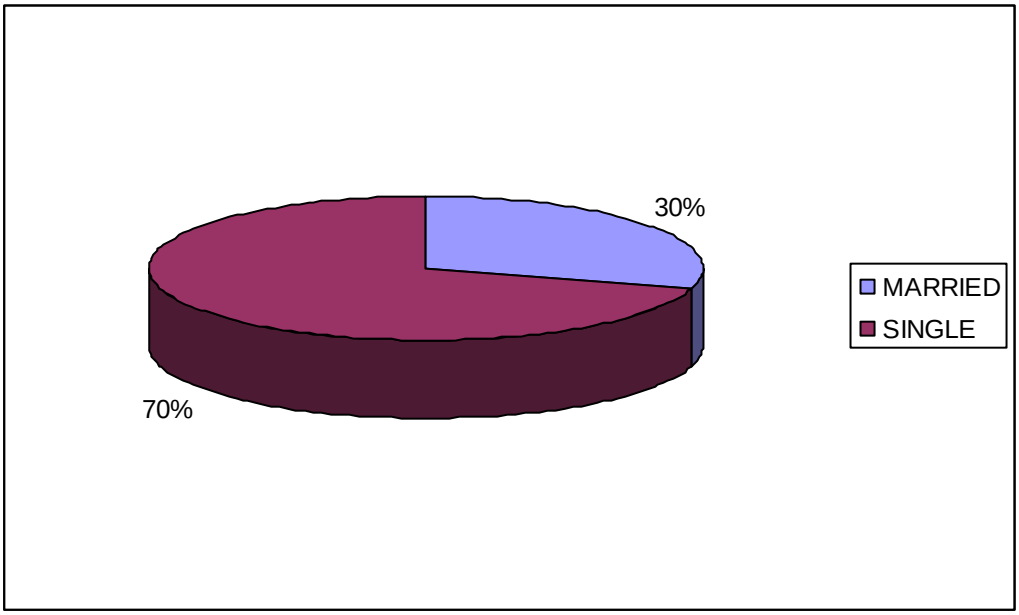

Figure 4.2 Percentage Marital Status Percentages

4.2. PROCEDURE 1 (INTRA-GROUP): FRIEDMAN TEST

4.2.1. Moos Menstrual Distress Questionnaire (*Appendix A)*

Table 4.1. Comparison for consultation one, two and three in Treatment Group.

	Mean Rank Consultation one	**Mean Rank Consultation two**	**Mean Rank Consultation three**	**P value**
Pain	2.42	2.00	1.58	.076
Concentration	2.38	2.08	1.54	.052
Behavioural changes	2.08	2.08	1.85	.679
Autonomic reactions	2.27	1.92	1.81	.197
Water retention	2.50	2.00	1.50	.020*
Negative affects	2.38	1.96	1.65	.168
Arousal	1.85	2.04	2.12	.690
Control	2.23	2.00	1.77	.313
Appetite changes	2.58	1.73	1.69	.010*

***Statistically significant*

Table 4.1. reveals the following:

Over the three consultations there was a statistical significance in water retention and appetite changes in the Treatment Group. There were no statistically significant changes in pain, concentration, behavioural changes, autonomic reaction, negative affects, arousal and control over the consultations in the Treatment Group.

Table 4.2. Comparison for consultation one, two and three in Placebo Group.

	Mean Rank Consultation one	**Mean Rank Consultation two**	**Mean Rank Consultation three**	**P value**
Pain	2.25	2.00	1.75	.360
Concentration	2.36	2.14	1.50	.029*
Behavioural changes	2.29	2.14	1.57	.078
Autonomic reactions	2.50	1.71	1.79	.013*
Water retention	2.46	1.75	1.79	.079
Negative affects	2.36	2.00	1.64	.125
Arousal	1.89	2.18	1.93	.572
Control	1.86	2.32	1.83	.175
Appetite changes	2.43	1.93	1.64	.035*

***Statistically significant*

Table 4.2. reveals the following:

In the Placebo Group there were statistically significant changes over the three consultations in the subgroups of concentration, autonomic reactions and appetite changes. There were no statistically significant changes in the subgroups of pain, behavioural changes, water retention, negative affects, arousal and control in the Placebo Group.

4.3 PROCEDURE 2 (INTRA-GROUP): WILCOXON SIGNED RANK TEST

Table 4.3. Comparison of scores for Water Retention and Appetite Changes between consultation one and consultation two (1-2), consultation two and consultation three (2-3), and consultation one and consultation three (1-3) in the Treatment Group

CONSULTATION	**1-2**	**2-3**	**1-3**
Water Retention (p value)	.070	.034*	.018*
Appetite Changes (p value)	.009*	.725	.013*

***Statistically significant*

Table 4.3. reveals the following:

Water retention: The statistically significant changes occurred between consultation two and consultation three, and between consultation one and consultation three in the Treatment Group.

Appetite changes: There was significant difference between consultation one and two, and between consultation one and consultation three in the Treatment Group.

Table 4.4. Comparison of scores for Concentration, Behavioural Changes, Autonomic Reactions and Appetite Changes between consultation one and consultation two (1-2), consultation two and consultation three (2-3), and consultation one and consultation three (1-3) in the Placebo Group

CONSULTATION	**1-2**	**2-3**	**1-3**
Concentration (p value)	.455	.060	.050*
Autonomic reactions (p value)	.013*	.750	.057
Appetite changes (p value)	.066	.083	.008*

***Statistically significant*

Table 4.4. reveals the following:

Concentration: There was a significant difference between consultation one and consultation three in the Placebo Group.

Autonomic Reactions: There was a significant difference between consultation one and two in the Placebo Group.

Appetite changes: There was a significant difference between consultation one and three in the Placebo Group.

4.4. **PROCEDURE 3 (INTER-GROUP): KRUSKAL-WALLIS TEST**

Table 4.5. Comparison of scores between Treatment and Placebo Groups at consultation one, two and three.

	Consultation one (p value)	**Consultation two (p value)**	**Consultation three (p value)**
Pain	.406	.733	.864
Concentration	1.000	.882	.958
Behavioural changes	.414	.218	.724
Autonomic reactions	.655	.637	.565
Water retention	.574	.540	.229
Negative affects	.923	.644	.304
Arousal	.221	.485	.247
Control	.439	.687	.852
Appetite changes	.452	.918	.335

***Statistically significant*

Table 4.5 reveals the following:

Pain: There were no significant differences (p>0.05).

Concentration: There were no significant differences (p>0.05).

Behavioural changes: There were no significant differences (p>0.05).

Autonomic reactions: There were no significant differences (p>0.05).

Water retention: There were no significant differences (p>0.05).

Negative affects: There were no significant differences ($p>0.05$).

Arousal: There were no significant differences ($p>0.05$).

Control: There were no significant differences ($p>0.05$).

Appetite changes: There were no significant differences ($p>0.05$).

4.5. BAR CHARTS COMPARING MEANS FOR SUBSCALES AND RELATED DESCRIPTIVE STATISTICS

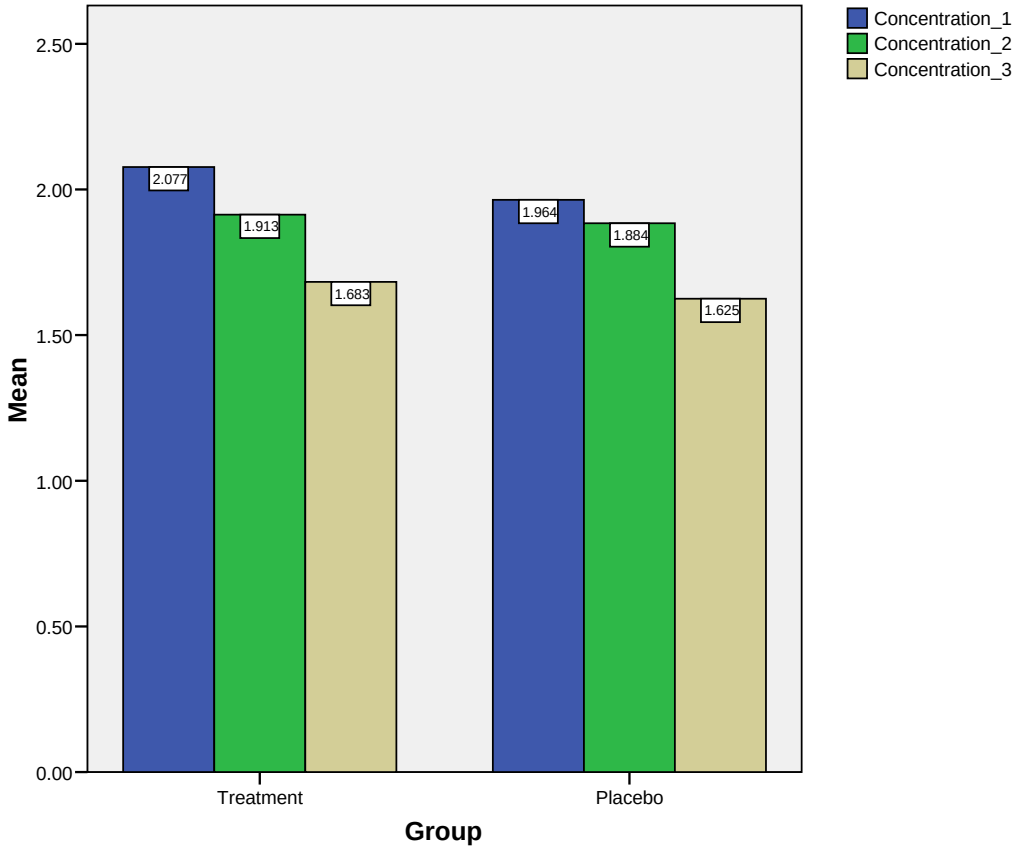

Figure 4.3 Bar Chart: Mean scores for Concentration

Figure 4.3 reveals that the scores for concentration difficulties were higher in the Treatment Group at the first consultation. At the second consultation, both groups showed an improvement. By the third consultation, both groups showed a further improvement.

Table 4.6 Descriptive Statistics for Concentration

Concentration	Consult	Min	Max	Mean	Std. deviation
Treatment Group	1	1.00	4.00	2.0769	1.04276
	2	1.00	4.38	1.9135	1.05251
	3	1.00	3.75	1.6827	0.93209
Placebo Group	1	1.00	4.20	2.1143	1.11138
	2	1.00	4.80	2.1143	1.18117
	3	1.00	3.40	1.6286	0.84801

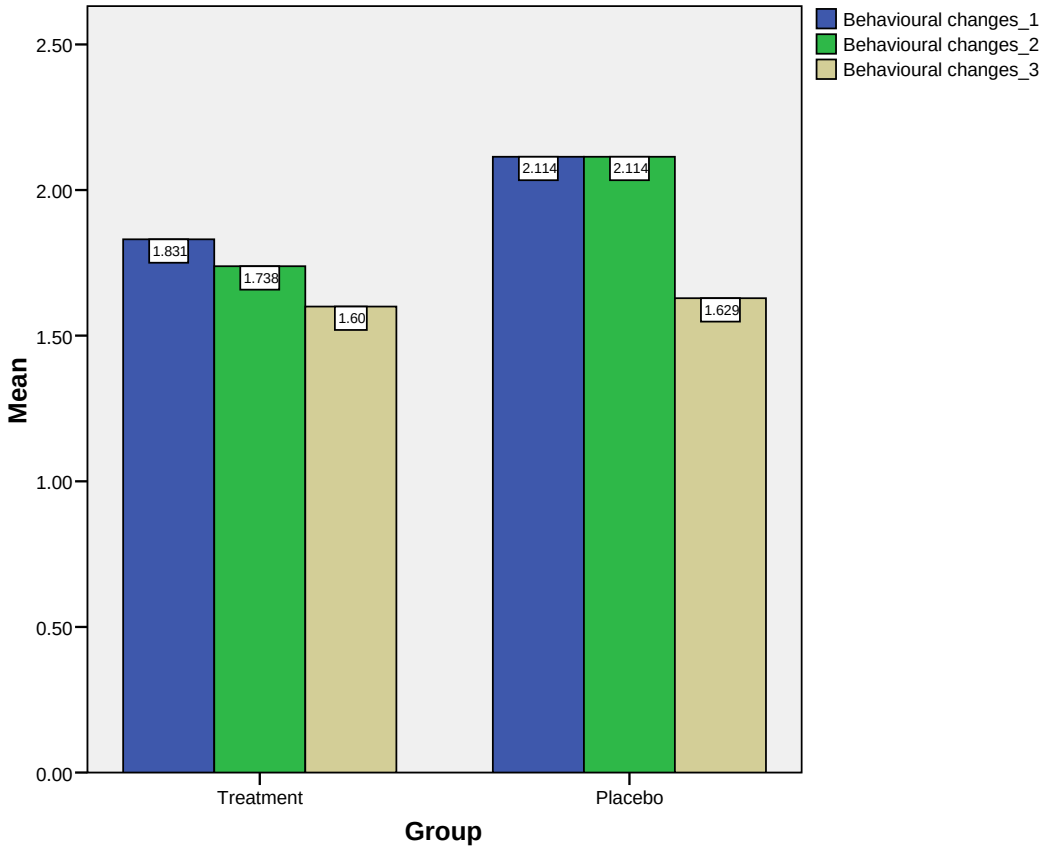

Figure 4.4 Bar Chart: Mean scores for Behavioural Changes

Figure 4.4 reveals that initially the mean scores for behavioural changes were higher in the Placebo Group. After the second consultation the Placebo Group showed no change in scores and the Treatment Group showed an improvement in the scores. By the third consultation, both groups showed an improvement.

Table 4.7 Descriptive Statistics for Behavioural Changes

Behavioural changes	Consult	Min	Max	Mean	Std. deviation
Treatment Group	1	1.00	4.00	1.8308	1.01274
	2	1.00	4.80	1.7385	1.18711
	3	1.00	4.20	1.6000	0.98319
Placebo Group	1	1.00	3.75	1.9643	0.83986
	2	1.00	4.13	1.8839	1.0196
	3	1.00	4.13	1.6250	0.97443

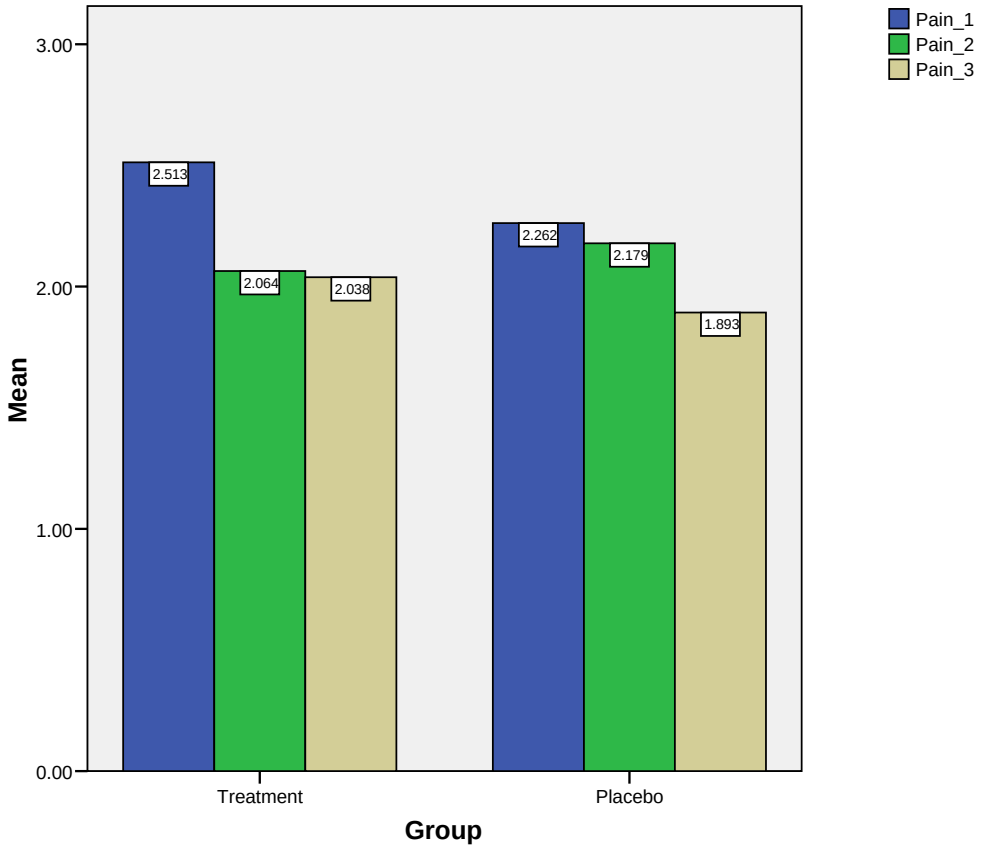

Figure 4.5 Bar Chart: Mean scores for Pain

Figure 4.5 reveals that mean scores for pain the Treatment Group had higher levels. At consultation two both groups showed a decrease in pain. By the third consultation, the Placebo Group showed a slightly greater improvement than the Treatment Group.

Table 4.8 Descriptive Statistics for Pain

Pain	Consult	Min	Max	Mean	Std. deviation
Treatment Group	1	1.00	4.33	2.5128	0.84289
	2	1.00	4.00	2.0641	0.98493
	3	1.00	3.50	2.0385	0.87176
Placebo Group	1	1.00	3.83	2.2619	0.70624
	2	1.00	3.83	2.1786	0.92326
	3	1.00	4.00	1.8929	0.81284

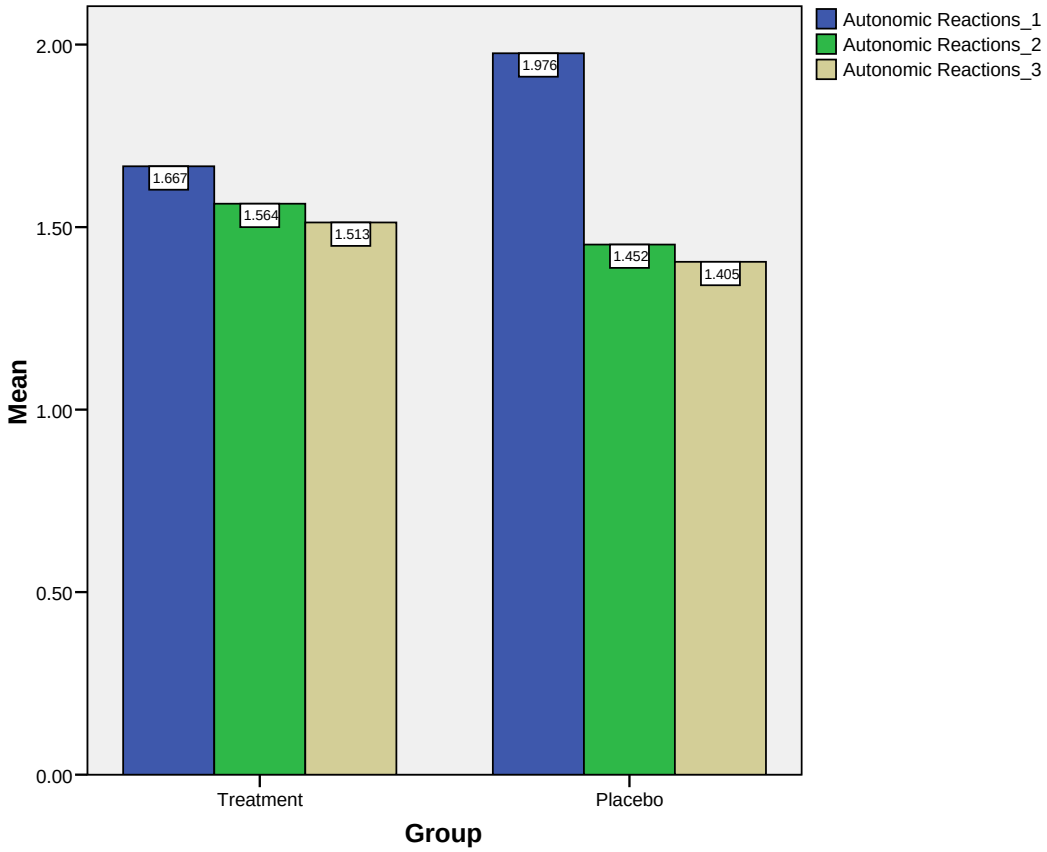

Figure 4.6 Bar Chart: Mean scores for Autonomic Reactions

Figure 4.6 reveals that mean scores for autonomic reactions the first consultation were higher for the Placebo Group. At the second consultation both groups showed an improvement with the Placebo Group showing a greater improvement. By the third consultation, both groups continued to improve but the overall improvement was greater in the Placebo Group.

Table 4.9 Descriptive Statistics for Autonomic Reactions

Autonomic Reactions	Consult	Min	Max	Mean	Std. deviation
Treatment Group	1	1.00	3.00	1.6667	0.72008
	2	1.00	3.33	1.5641	0.80949
	3	1.00	5.00	1.5128	1.08539
Placebo Group	1	1.00	5.00	1.9762	1.22972
	2	1.00	3.33	1.4524	0.73505
	3	1.00	4.67	1.4048	0.9712

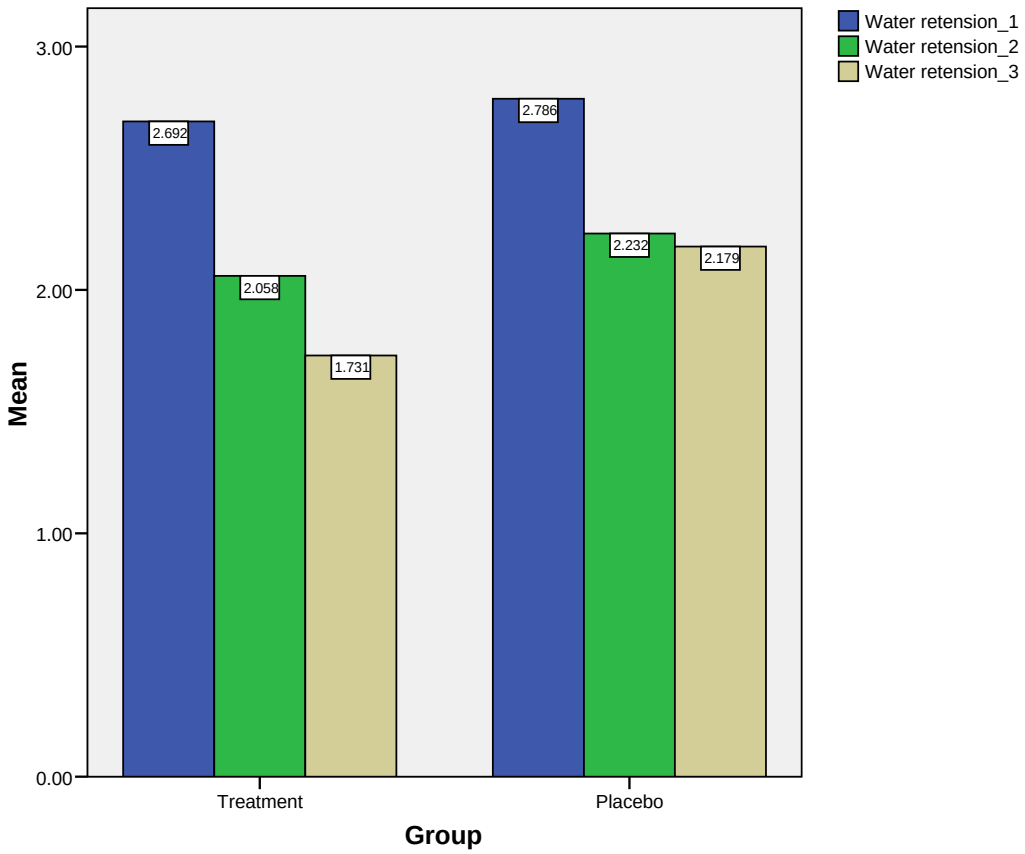

Figure 4.7 Bar Chart: Mean scores for Water Retention

Figure 4.7 reveals that mean scores for water retention at the first consultation were almost equal. At the second consultation, both groups showed an improvement. By the third consultation, the Treatment Group showed a greater improvement than the Placebo Group.

Table 4.10 Descriptive Statistics for Water Retention

Water Retention	Consult	Min	Max	Mean	Std. deviation
Treatment Group	1	1.00	5.00	2.6923	1.39625
	2	1.00	3.25	2.0577	0.90803
	3	1.00	3.00	1.7308	0.71779
Placebo Group	1	1.00	3.75	2.7857	0.73939
	2	1.00	3.25	2.2321	0.79339
	3	1.00	3.75	2.1786	0.95791

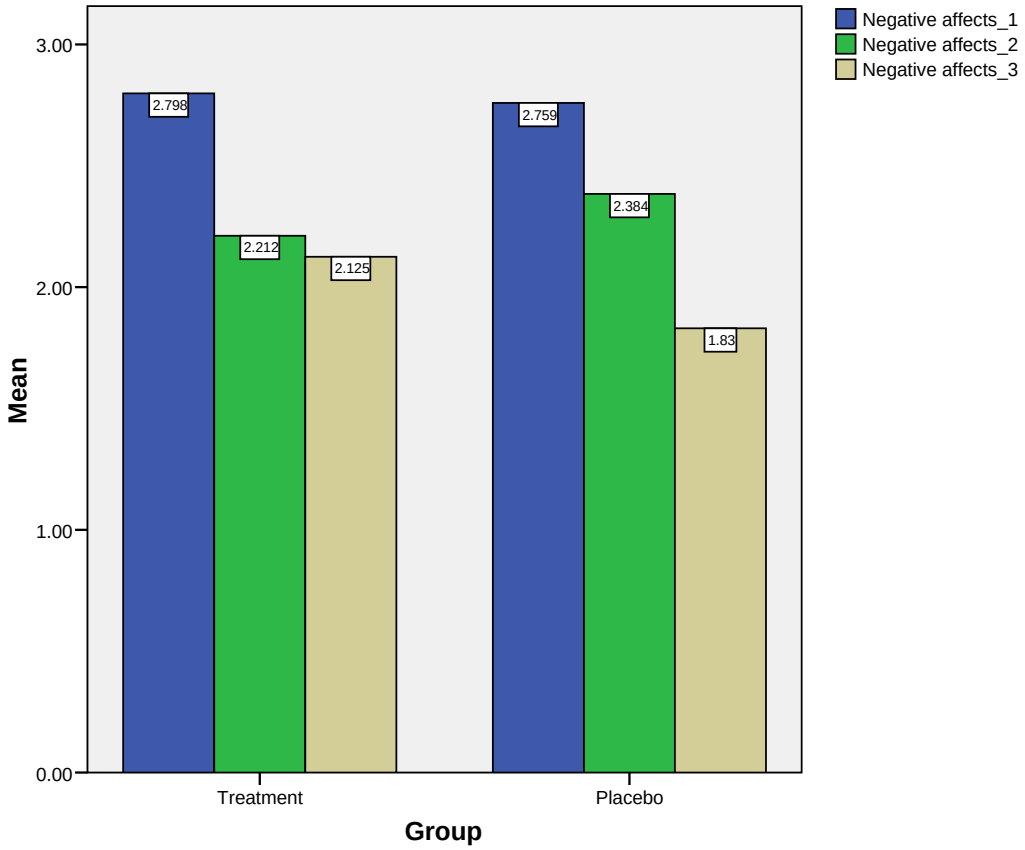

Figure 4.8 Bar Chart: Mean scores for Negative Affects

Figure 4.8 reveals that mean scores for negative affects were equal at first consultation. At the second consultation both groups improved with the Treatment Group having a slightly greater improvement. By the third consultation, the Placebo Group showed a great improvement whilst the Treatment Group had a moderate improvement.

Table 4.11 Descriptive Statistics for Negative Affects

Negative Affects	Consult	Min	Max	Mean	Std. deviation
Treatment Group	1	1.00	4.38	2.7981	1.27326
	2	1.00	4.25	2.2115	1.12545
	3	1.00	3.88	2.1250	1.0039
Placebo Group	1	1.00	4.25	2.7589	0.97747
	2	1.00	4.88	2.3839	1.20342
	3	1.00	4.38	1.8304	0.94004

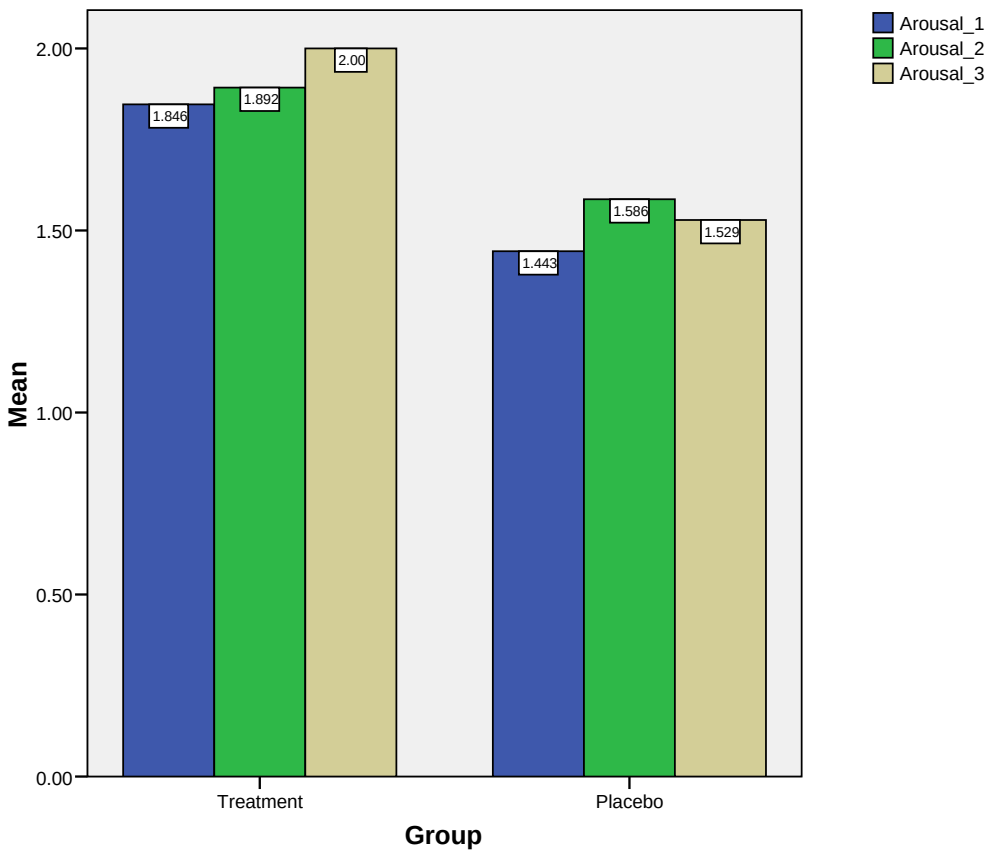

Figure 4.9 Bar Chart: Mean scores for Arousal

Figure 4.9 reveals that mean scores for arousal were greater in the Treatment Group than the Placebo Group. At the second consultation both groups showed higher scores. By the third consultation the Treatment Groups' score continued to increase but the Placebo Groups score decreased slightly.

Table 4.12 Descriptive Statistics for Arousal

Arousal	Consult	Min	Max	Mean	Std. deviation
Treatment Group	1	1.00	3.40	1.8462	0.85695
	2	1.00	3.60	1.8923	0.95084
	3	1.00	3.60	2.0000	0.98658
Placebo Group	1	1.00	3.60	1.4429	0.70243
	2	1.00	3.00	1.5857	0.69488
	3	1.00	2.80	1.5286	0.68661

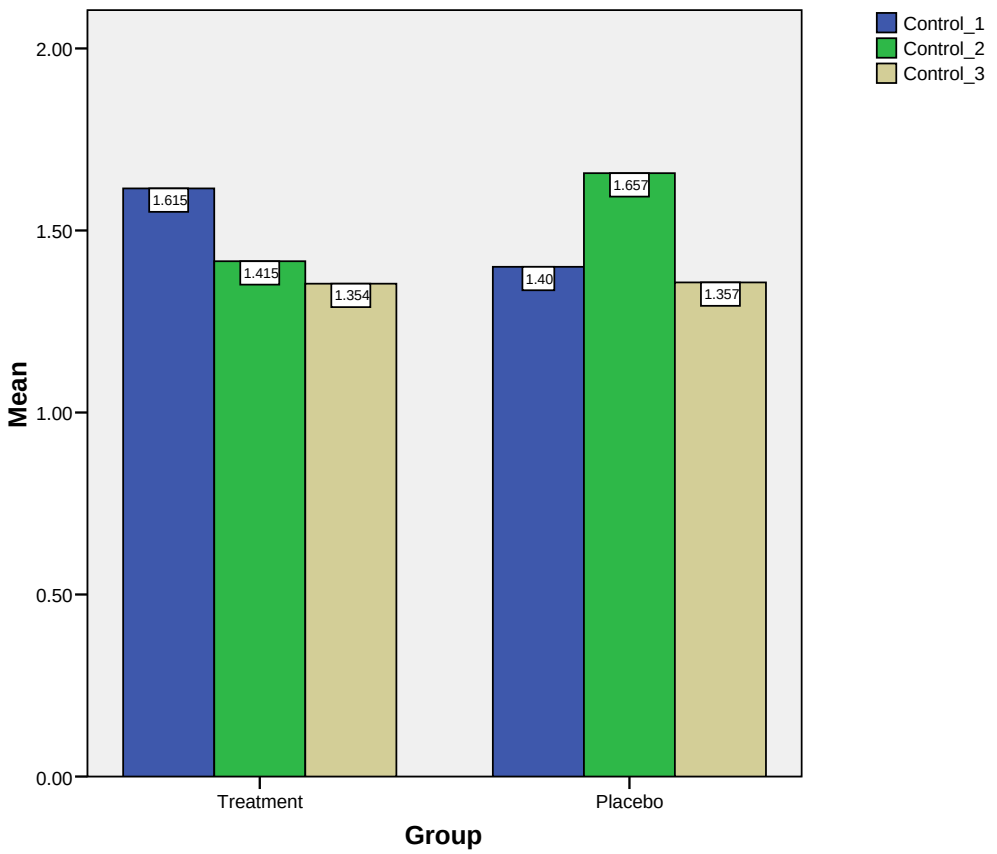

Figure 4.10 Bar chart: Mean scores for Control

Figure 4.10 reveals that the mean scores at the first consultation were higher in the Treatment Group. At consultation two, the Treatment Group showed an improvement and the Placebo Group a deterioration in scores. By the third consultation, the Treatment Group showed further improvement and the Placebo Group improved from consultation two with a slight improvement from the original score at consultation one.

Table 4.13 Descriptive Statistics for Control

Control	Consult	Min	Max	Mean	Std. deviation
Treatment Group	1	1.00	3.00	1.6154	0.70928
	2	1.00	2.80	1.4154	0.55052
	3	1.00	2.20	1.3538	0.47013
Placebo Group	1	1.00	3.40	1.4000	0.67482
	2	1.00	3.80	1.6571	0.86087
	3	1.00	3.00	1.3571	0.63816

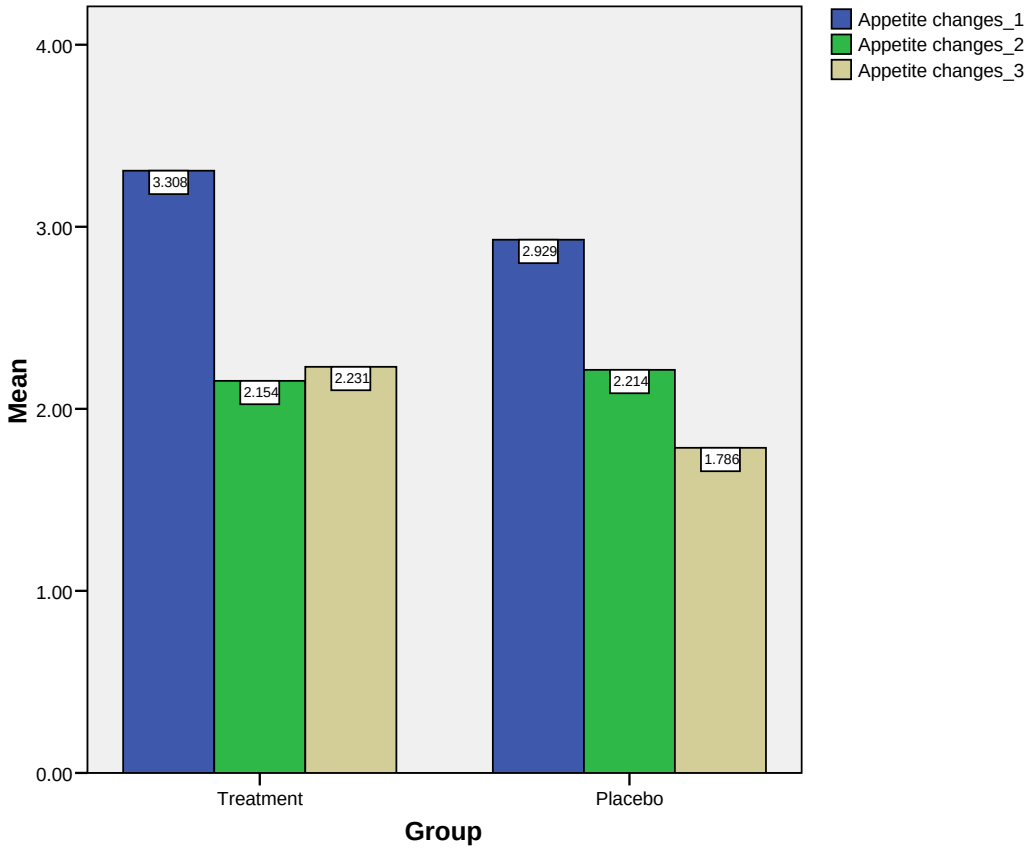

Figure 4.11 Bar Chart: Mean scores for Appetite Changes

Figure 4.11 reveals that mean scores for appetite changes at consultation one were higher in the Treatment Group. At consultation two, appetite changes scores for the Treatment and Placebo Groups showed an improvement. By the third consultation, the Placebo Group continued to improve and the Treatment Group showed a slight worsening of scores.

Table 4.14 Descriptive Statistics for Appetite Changes

Appetite changes	Consult	Min	Max	Mean	Std. deviation
Treatment Group	1	1.00	5.00	3.3077	1.37747
	2	1.00	4.00	2.1538	1.21423
	3	1.00	4.00	2.2308	1.30089
Placebo Group	1	1.00	5.00	2.9286	1.26881
	2	1.00	5.00	2.2143	1.42389
	3	1.00	5.00	1.7857	1.3114

4.6. **HOMOEOPATHIC REMEDIES PRESCRIBED**

4.6.1. Total Homoeopathic remedies prescribed

Remedies were prescribed at the first consultation for each participant, there was one remedy prescribed.

Table 4.15 Total remedies prescribed throughout the study

Carcinosin	4
Sepia officinalis	4
Calcarea carbonica	3
Arsenicum album	2
Natrum muriaticum	6
Ignatia amara	2
Sulphur	1
Nux vomica	1
Silica	1
Phosphorus	1
Pulsatilla nigrans	1
Lachesis mutas	1

Table 4.15 reveals that the 4 most frequently prescribed remedies in the study were *Natrum muriaticum, Carcinosin, Sepia officinalis* and *Calcarea carbonica*.

4.6.2. Remedies prescribed in the Treatment Group

Table 4.16 Remedies prescribed in the Treatment Group

Sepia officinalis	2
Calcarea carbonica	3
Arsenicum album	1
Natrum muriaticum	5
Silica	1
Pulsatilla nigrans	1

4.6.3. Remedies prescribed in the Placebo Group

Table 4.17 Remedies prescribed in the Placebo Group

Carcinosin	4
Sepia officinalis	2
Arsenicum Album	1
Natrum muriaticum	1
Ignatia amara	2
Sulphur	1
Nux vomica	1
Phosphorus	1
Lachesis mutas	1

CHAPTER 5

5.1. STUDY OBJECTIVES

This double-blind placebo-controlled study was conducted to determine the effectiveness of homoeopathic simillimum in the treatment of premenstrual syndrome (PMS). Outcomes were assessed in terms of participants' perception of treatment, using the Menstrual Distress Questionnaire (Appendix A).

5.2. THE MOOS MENSTRUAL DISTRESS QUESTIONNAIRE (MDQ)

5.2.1. Intra-group analysis

Table 4.1 demonstrates that the Treatment Group showed a significant difference in the reduction of symptoms in the subgroups of water retention (p=.020) and appetite changes (p=.010) during the trial. Table 4.3 demonstrates that the significant difference in regard to water retention occurred between the first and third consultation (p=.034) and between the second and third consultation (p=.018). Table 4.3 indicates the difference in appetite changes occurred between the first and second consultation (p=.009) and between the first and third consultation (p=.013). No significant difference was noted in the subgroups of pain (p=.076), concentration (p=.052), behavioural changes (p=.679), autonomic reactions (p=.197), negative affects (p=.168), arousal (p=.690) or control (p=.313) in the Treatment Group.

Table 4.2 demonstrates that the Placebo Group showed a significant difference in the reduction of symptoms in the subgroups of concentration (p=.029), autonomic reactions (p=.013) and appetite changes (p=.035) during the trial. No significant differences were noted in the subscales of pain (p=.360), behavioural changes (p=.078), water retention (p=.079), negative affects (p=.125), arousal (p=.572), and control (p=.175). Table 4.4 indicates that the significant difference in autonomic reactions occurred between the

first consultation and the second consultation (p=.013). The significant differences in concentration (p=.050) and appetite changes (p=.008) occurred between the first and third consultation.

5.2.2. Inter-group analysis

Inter-group analysis for all aspects of the MDQ questionnaire revealed no statistically relevant results (table 4.5), and hence the null hypothesis was accepted.

5.2.3. Conclusion – MDQ

The statistical evidence indicates that homoeopathic simillimum is ineffective in the treatment of PMS.

5.3. LIMITATIONS OF THE STUDY DESIGN: A POST-HOC ANALYSIS

5.3.1. Participant Compliance

PMS is a chronic condition so the study should have been conducted over a longer time period for the effect of homoeopathic simillimum to be adequately examined. The researcher feels that the limited duration of the study would not have effectively shown the efficacy of the treatment. The research should have incorporated telephonic follow up consultations in the study design as this would have combated a large number of participant withdrawals from the study due to poor accessibility at the Homoeopathic Day Clinic due to various events outside of the researcher's control.

5.3.2. Sample Size

Due to participant non-compliance the researcher had to reduce sample size. The initial sample size should have been larger to account for non-compliance and withdrawals so that the final sample size would still be large enough to

make the study statistically viable. This would have indicated a true reflection of the effect of homoeopathic simillimum on PMS.

5.3.3. Prescription

The study utilised three single unit homoeopathic powders (active/ placebo) followed by 20ml homoeopathic liquid (active/ placebo) remedies, which were given in drop form on a daily basis. The powder medicines were taken consecutively on a daily basis from day 10 of the menstrual cycle (10 days after onset on menstruation). The liquid medicine was taken daily from day 13 of the menstrual cycle (13 days after the onset of menstruation) and continued daily till the onset of the following menstrual cycle. The participants took the remedies for a single menstrual cycle and then had no further treatment.

The researcher believes a daily remedy/placebo for the duration of the study would have improved overall compliance. Administration of medication (active/placebo) should have taken place at each consultation as this would have given the researcher the option to repeat the simillimum if need be or to give placebo treatment. This would have simply acted as a daily reminder of the research being conducted which may have helped with overall compliance in the study. The repetition of prescription would negate the effect of life stressors interrupting the study. The participants experienced great stress over the research period, for example: examinations, marriage preparation, pregnancy scares, crime and others. All of which serve as interference to a clear indication of the effect of homoeopathic simillimum.

5.3.4. Outcome measures

The use of a single outcome measurement tool was exceedingly limiting in assessing the efficacy of the condition, especially since the questionnaire was completed monthly post-menstruation and relied upon the participant's recollection. Participants were not always clear about the meaning of the different categories of the questionnaire, which may have led to mis-information. The researcher should have given clear definitions of the

categories in the pre-research literature to prevent confusion with regards to meanings. In addition to the MDQ the researcher should have elected to use a daily rating scale of symptoms. The participants would then have completed a questionnaire daily and the researcher would use the scores for the 7 days before the menstrual cycle to indicate the premenstrual scores. The act of recording symptoms daily would serve as a reminder that they are participating in a study and so would improve compliance. It would also increase the accuracy of the results as the scores are not based on recollection but at the time the participant experienced them. The MDQ would still be done at each consultation using the scores for the 7-10 days before the menstruation. The use of a second outcome measure would improve overall accuracy in recording efficacy of treatment.

5.3.5. Inexperience of the researcher

Implicit to the identification of the simillimum is the homoeopath. Different practitioners vary in age, gender, expertise, experience and approach. Thus the results of any trial involving the simillimum are as much an evaluation of the practitioner as it is the modality (Bloch, 2002:59). Although the researcher received clinical supervision, it must be noted that she is relatively inexperienced.

The relative lack of experience on the part of the researcher may have accounted for the prescription of broader acting remedies, such as *Natrum muriaticum*, because the case-taking skills of the researcher were not as honed as an experienced homoeopath, and so the nuances of smaller remedies would be missed during consultation. However, the remedies prescribed during the trial were all well indicated based on the information gained from the participant. In a homoeopathic case there is some information, which is objective but the majority of the information is subjective or qualitative which is where the homoeopath's case-taking/counselling skills come into consideration. The interpretation of the information gained is varied with experience and skill level of the homoeopath.

Swayne (1998:41) and Scholten (2002:825) state that the skill and experience of the individual homoeopath is an important factor in determining the use of remedies, and application of the simillimum method; consequently it will influence treatment outcomes.

Even with the inexperience of the researcher many participants noted an improvement in general well being. Two of the women on active treatment noted a complete 180 degree turn around of symptoms with energy levels improving, sleep improving and general motivation to improve their lives increasing. These improvements were only noted during the month of treatment and not in the following observational month. However the scores at the end of the trial were better than at the beginning (only by a small margin).

5.4. PLACEBO EFFECT

Placebo is any therapeutic procedure (or component of therapeutic procedure) which is deliberately given to have effect on, a symptom, syndrome or disease, but which is without specific activity for a condition being treated (Liggins, 2002). In this study the consultation itself is a placebo as it brings about improvements non-specific to the complaint. Most of the participants reported changes to their general well being other than that relating to PMS irrespective of which group they were allocated to in the trial.

PMS has often reported high rates of positive response to placebo (Freeman *et al*, 1999). The changes noted in both groups, even if not statistically significant, did comply with the above statement. The act of acknowledgement of PMS as a real complaint and the suggestion of receiving a treatment for it was enough to cause a clinical change.

5.4.1. Placebo group

Sarawan (2001) found that in some aspects of his study the placebo out-performed the complex. Kirtland (1995) found that in her study conducted to compare placebo to homoeopathic preparation of Folliculinum 15CH, that the

placebo group only experienced a 7% improvement at the end of the trial in comparison to the 89% improvement found in the Treatment Group.

Intra-group analyses revealed that concentration, autonomic response and appetite changes all had significant improvement on placebo, which indicated a psychological aspect of the condition. The case-taking process may account for the improvements in the homoeopathic consultation, which allows the participants to express themselves in a caring, quiet and empathetic environment, which causes positive changes in their lives.

5.4.2. Treatment Group

If the therapeutic potential of the consultation played a role in the placebo group there is a high likelihood that it had a possible influence in the Treatment Group. Assuming this to be the case, the positive affects seen in the Treatment Group could simply be due to the placebo effect, especially considering how similar the overall changes were between the two groups.

5.5. HOMOEOPATHIC ANALYSIS

Remedies most often prescribed in the research were: *Natrum muriaticum, Carcinosin*, *Sepia officinalis* and *Calcarea carbonica.*

Natrum muriaticum (sea salt) was the most prescribed remedy with 12 prescriptions being *Natrum muriaticum* of the total 39 prescriptions made up in the research. Of this group 6 completed the study. It was apparent that many of the women experiencing PMS had to be “in control of themselves to protect themselves and keep their lives together”. This is a common trend in the *Natrum muriaticum* women. *Natrum muriaticum* women are very sensitive and protect themselves by working through hurts and “walling off” their feelings. Their bodies do not necessarily comply with this mentality and, therefore, manifest physically what they refuse to manifest emotionally. This occurs around the time of menstruation. *Natrum muriaticum* is averse to consolation or company and may have periods of involuntary and hysterical

weeping. *Natrum muriaticum* is also known for symptoms of water retention due to the very nature of sea salt and its affiliation for attracting water.

Some PMS symptoms experienced by *Natrum muriaticum*:

- Aggravation before menses
- Involuntary and hysterical weeping
- Depression
- Headache before menses
- Craving salt
- Insomnia
- Feeling trapped
- Anaemia
- Aversion to sex
- Water retention
- Fastidious

(Vermeulen, 2002:958-967)

Carcinosin was prescribed 4 times out of the total 39 prescriptions. All 4 participants completed the study. *Sepia officinalis* was prescribed 5 times out of the total 39 prescriptions and of these, 4 completed the study and were able to be used for statistical purposes. *Calcarea carbonica* was prescribed 4 times out of the total 39 prescriptions and of these, 3 completed the study.

5.6. DEMOGRAPHICS OF THE PMS TRIAL

PMS is a female condition, and therefore, all the participants were female. The age restriction of the study was 18 to 40 years of age. The age profile of the 27 women that completed the study was, 3 between the ages of 18-21 (11%), 11 between the ages of 22-25 (41%), 7 between the ages of 26-30 (26%), 3 between the ages of 31-35 (11%) and 3 between the ages of 36-40 (11%). There were 8 married participants (30%) and 19 single participants (70%). These statistics may not accurately reflect the demographical spread of PMS as the researcher used convenience sampling. The research was

conducted at a tertiary education institution which may have skewed the demographic profile of PMS due to the increased accessibility of single females under the age of 25. In a different setting where the accessibility of women would be more diverse the demographic profile would have shown a more accurate reflection of PMS in society.

5.7. CONCLUSION

There was an overall clinical improvement in both groups even though it was not statistically significant. Therefore due to statistical parameters homoeopathic simillimum was found to be ineffective in the treatment of PMS.

CHAPTER 6

6.1. CONCLUSION

The results of this study led to the conclusion that statistically, the homoeopathic simillimum was not effective in the treatment of Premenstrual Syndrome although there was an improvement in both groups.

6.2. RECOMMENDATIONS

The following recommendations are made for further research:

1. Daily diaries should be used rather than a monthly questionnaire in studies involving changes occurring over a menstrual cycle.
2. Conduct the study over a longer time period with repeated prescriptions rather than a single prescription due to the chronic nature of PMS.
3. Allow for prescriptions to be repeated to account for any life event that may alter or interfere with the treatment.
4. Use a larger sample size to allow for greater statistical accuracy.
5. Select a setting that is more accessible to the general public - possibly away from the Homeopathic Day Clinic.
6. Conduct a pragmatic study into the benefits of homoeopathy treatment in conjunction with other complementary therapy as a long-term treatment for PMS.
7. Compare the efficacy of homoeopathic simillimum to a homoeopathic complex and placebo in the treatment of PMS.
8. Conduct a study comparing the efficacy of homoeopathic treatment to one of the other complementary treatment professions e.g. chiropractic, reflexology, acupuncture.
9. Compare the economic viability and effectiveness of homoeopathic treatment against one of the allopathic treatments.

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APPENDIX A

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE

(This is the original questionnaire as developed by Moos, 1968)

Patient: _____

Entry No. : _____

Write the appropriate date of your most recent menstrual flow:

A: Most recent flow from _____to _____.
B: week before the most recent flow.
C: other times during the cycle.

Write the date of the menstrual flow that preceded the most recent flow:

D: flow preceding the most recent menstrual flow _____to _____.

On the following pages is list of symptoms that women sometimes experience. Please describe your experience of these symptoms during the three different periods listed before:

Column 1: during the most recent menstrual flow (A)
Column 2: one week before the menstrual flow (B)
Column 3: during the remainder of your most recent menstrual cycle (C)

Note: The answers you put in column 1, 2 and 3 should describe your experience specifically during your **most recent menstrual cycle**. Please do not report your general symptoms. Please report if the symptoms are related to your menstrual cycle or not.

For each answer choose the category listed below which best describes your experience of each symptoms during that particular time. Write the number of that category in the space provided below. If none of the options accurately describe the symptoms, please choose an option that is closest to your experience.

CATEGORIES:

1 = no experience of symptoms
2 = barely noticeable
3 = present, mild
4 = present, strong
5 = acute or partially disabling

CATEGORIES:

1 = no experience of symptoms
2 = barely noticeable
3 = present, mild
4 = present, strong
5 = acute or partially disabling

	Most recent flow (A)	**The week before (B)**	**Rest of the month (C)**
Muscle Stiffness			
Headaches			
Cramps			
Backache			
Fatigue			
General aches and pains			
Insomnia			
Forgetfulness			
Confusion			
Lowered judgement			
Difficulty concentrating			
Distractible			
Accident prone			
Lowered motor coordination			
Lowered school / work performance			
Take naps; stay in bed			
Stay at home			
Avoid social activities			
Decreased efficiency			
Dizziness, faintness			
Nausea, vomiting			
Hot flushes			
Weight gain			
Skin disorders			
Painful breasts			
Swelling			
Crying			

CATEGORIES:

1 = no experience of symptoms
2 = barely noticeable
3 = present, mild
4 = present, strong
5 = acute or partially disabling

	Most recent flow (A)	**The week before (B)**	**Rest of the month (C)**
Loneliness			
Anxiety			
Restlessness			
Irritability			
Mood swings			
Depression			
Tension			
Affectionate			
Orderliness			
Excitement			
Feeling of well-being			
Burst of energy, activity			
Feeling of suffocation			
Chest pain			
Ringing in the ears			
Heart pounding			
Blind spots, fuzzy vision			
Change in eating habits			

SYMPTOMS SCALES ON THE MOOS MENSTRUAL DISTRESS QUESTIONNAIRE

PAIN
Muscle stiffness
Headaches
Cramps
Fatigue
General aches and pains
Backache

CONCENTRATION
Insomnia
Forgetfulness
Confusion
Lowered judgement
Difficulty concentrating

BEHAVIOURAL CHANGES
Lowered school/work performance
Take naps; stay in bed
Stay at home
Avoid social activities
Decreased efficiency

AUTONOMIC REACTIONS
Dizziness
Nausea, vomiting
Hot flushes

WATER RETENTION
Weight gain
Skin disorders
Painful breasts
Swelling

NEGATIVE AFFECT
Crying
Loneliness
Anxiety
Restlessness
Irritability
Mood swings
Depression
Tension

AROUSAL
Affectionate
Orderliness
Excitement
Feeling of well-being
Bust of energy, activity

CONTROL
Feeling of suffocation
Chest pains
Ringing in the ears
Heart pounding
Blind spots, fuzzy vision

APPETITE CHANGES

APPENDIX B

Attention Ladies

- Breast swelling and tenderness
- Fatigue and trouble sleeping
- Upset stomach, bloating, constipation or diarrhoea
- Headaches
- Appetite changes or food cravings
- Joint or muscle pain
- Tension, irritability, mood swings or crying spells
- Anxiety or depression
- Trouble concentrating or remembering

If you experience any of the symptoms mentioned above 2-10 days before your period you may be experiencing **Premenstrual Syndrome (PMS).**

Research is currently being conducted at the Durban University of Technology's Homeopathic Clinic.
You may qualify for free **PMS** treatment.

If you are female, between the age of 18-40 and suffer from PMS, call:
Carrie 073 624 3222
For a free consultation.

APPENDIX C

Is that time of the month getting you down?

You may qualify for Free Treatment
For
Premenstrual Syndrome/Tension (PMS/PMT).

Homoeopathic Research is currently being done at DIT.

If you are female and between the age of 18-40 and suffer from PMS, call:
Carrie 073 628 3222
Or the homoeopathic day clinic 031 204 2041
For a consultation

APPENDIX D
Subject Information letter

TITLE OF RESEARCH PROJECT: The efficacy of Homoeopathic simillimum in the treatment of Premenstrual syndrome.
NAME OF SUPERVISOR: Dr M.Maharaj (M.Tech. Hom)
NAME OF INVESTIGATOR: Carrie-Ann Payne

DATE:

Dear Participant

Thank you for your time and interest in reading this letter. With your assistance the efficacy of the Homoeopathic simillimum treatment in premenstrual syndrome (PMS) can be investigated.

I am a master's student of the Durban Institute of Technology. In order to qualify as a Homoeopath, a dissertation has to be completed. This is a legitimate study and will test the efficacy of the homoeopathic treatment in alleviating the symptoms of PMS. In order to do this, I appeal to you for your assistance by becoming actively involved and informing me about your symptoms as well as their effect on your daily life.

This double-blind placebo controlled clinical trial will be conducted at the Homoeopathy Day Clinic during the afternoon sessions under the supervision of a qualified and registered homoeopath.

Each participant must comply with the selection criteria in order to participate in this study. The study will include those that fulfil the following criteria:

a) Individuals must be between 18-40 years of age.
b) Only menstruating females will be accepted
c) Individuals have symptoms in the 2-14 days before menstruation
d) Individuals must have a regular menstrual cycle.
e) Individuals must be literate.
f) Individual must meet the Diagnostic criteria for Premenstrual Syndrome.
    1. Symptoms must occur exclusively during the second half of the menstrual cycle.
    2. Symptoms increase in severity as the cycle progresses.
    3. Symptoms must be relieved by the onset of full menstrual flow.
    4. There must be an absence of symptoms in the postmenstruum.
    5. Symptoms have to be present for at least 2 consecutive cycles

Those with the following conditions will be excluded from the study:

a) Pregnant or breast-feeding females
b) Individuals on any treatment for premenstrual symptoms
c) Individuals who have started within the last 6 months on oral contraceptive pill or have changed oral contraceptive pill in the last 6 months.

Once you have fulfilled these selection criteria, you will be accepted into the study group. This study will last for three menstrual cycles (about 3 months) and the researcher will need to see you for three consultations during the month's i.e. the first consultation, second consultation and third/final consultation. During these consultations, you will be required to fill in the Menstrual Distress Questionnaire. All the information given by the participant will be kept confidential during the study.

This is a double-blind placebo controlled study where the participants will be divided randomly into two groups: 15 participants will be placed in the treatment group and 15 participants will be placed in the placebo group. The treatment and placebo group are medication indistinguishable from each other. The placebo group will receive an un-medicated form of the medication. Placebo has no effect and is medically considered inert so there is no risk involved in taking the placebo treatment. The treatment group may benefit by a reduction or cessation of premenstrual symptoms. Treatment will be available in the form of homoeopathic powders and drops that will be dispensed by the homoeopathic clinic dispenser. The placebo group will receive free treatment at the end of the study. There is a 50% chance of receiving placebo.

Your participation in this study is on a voluntary basis and will not cost you anything; the consultation and medicines are covered by the Durban Institute of Technology. You are welcome to withdraw from this study at anytime and without giving any reasons.

If you have any questions about the study or are experiencing any problems during the course of the study, please contact me or my supervisor on the following numbers:

Dr Maharaj 031 204 2041

Carrie-Ann Payne 031 904 1558 or 073 628 3222

Thank you for the courtesy of your assistance.

Department of Homoeopathy, Durban Institute of Technology.

APPENDIX E

INFORMED CONSENT FORM

(To be completed in duplicate by patient)

Date:

Title of Research project:	The efficacy of Homoeopathic simillimum in the treatment of Premenstrual syndrome.
Name of Supervisor:	Dr Madhu Maharaj (M.Tech. Hom)
Name of Research student:	Carrie-Ann Payne

Please circle the appropriate answer	**YES**	**NO**
1. Have you read the research information sheet?	Yes	No
2. Have you had an opportunity to ask questions regarding this study?	Yes	No
3. Have you received satisfactory answers to your questions?	Yes	No
4. Have you had an opportunity to discuss this study?	Yes	No
5. Have you received enough information about this study?	Yes	No
6. Who have you spoken to?_____		
7. Do you understand the implications of your involvement in this study?	Yes	No
8. Do you understand that you are free to withdraw from this study?	Yes	No
a) at any time		
b) without having to give any a reason for withdrawing, and		
c) without affecting your further health care.		
9. Do you agree to voluntarily participate in this study?	Yes	No
10. Do you understand that you may receive a placebo during the study?	Yes	No
11. Do you understand the difference between a placebo and homoeopathic treatment?	Yes	No

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

Please Print in block letters:

Patient/Subjects Name: _____ Signature: _____

Witness Name: _____ Signature: _____

Research Student Name _____ Signature: _____

APPENDIX F

Carrie-Ann Payne - Randomisation Sheet

(complied by Dr. M Maharaj on 30/03/06)

Patient number	Treatment	Placebo	Comment
1		X	Withdrew
2		X	
3	X		
4	X		
5	X		
6		X	Withdrew
7	X		
8		X	Withdrew
9		X	Withdrew
10	X		
11		X	Withdrew
12		X	
13	X		
14		X	
15		X	Withdrew
16		X	
17	X		
18	X		
19	X		
20	X		
21		X	
22	X		
23		X	
24	X		Withdrew
25		X	
26		X	
27	X		Withdrew
28	X		Withdrew
29		X	
30	X		
1A		X	
6A		X	
8A		X	
9A		X	Withdrew
11A		X	
15A		X	
24A	X		Withdrew
27A	X		
28A	X		Wtihdrew

APPENDIX G

DIAGNOSTIC CRITERIA OF PREMENSTRUAL SYNDROME (Dalton, 1984)

(This is the original criteria as developed by Dalton)

The criteria for a diagnosis of Premenstrual syndrome are:

1. Symptoms must occur exclusively during the second half of the menstrual cycle.

   Yes / No

2. Symptoms increase in severity as the cycle progresses.

   Yes / No

3. Symptoms must be relieved by the onset of full menstrual flow.

   Yes / No

4. There must be an absence of symptoms in the postmenstruum.

   Yes / No

5. Symptoms have to be present for at least 2 consecutive cycles.

   Yes / No

If all the above criteria have been met the patient may be accepted into the study.

PATIENT NAME: _____

ENTRY NO: _____

Symptoms referred to could be any of the following:

depression, anxiety, irritability, lack of concentration, memory loss, moodiness, tension, apathy, a feeling of being 'got at', difficulty in decision making, negativity, anger at others or at self, violent behaviour, tearfulness, lack of confidence, lack of sexual feeling, headaches and migraines, bloatedness, breast tenderness, acne, bowel problems, increased urinary frequency, hot flushes, nausea, aches and pain, increased appetite, food cravings, weight gain, clumsiness, tiredness and sleep disturbances. (Hayman, 1996)

APPENDIX H

PERSONAL DETAIL FORM

Please complete the following:
Please print.

1. Name: _____
2. Age: _____
3. Marital Status: _____
4. Occupation: _____
5. Age at which menstruation began:
   (When did you have your first period?) _____
6. When are your symptoms worse? _____
7. How long do your symptoms last for? _____
8. Do you take any medication to alleviate the symptoms? _____
9. If answered YES, what medication do you use? _____

   _____
10. Do you have any children, and if so, how many? _____
11. Present weight: _____