



**The efficacy of a Homoeopathic complex *Sepia officinalis* 30CH, *Pulsatilla pratensis* 30CH, *Passiflora incarnata* 30CH, *Kalium phosphoricum* 30CH and *Natrum muriaticum* 30CH in the management of Premenstrual Dysphoric Disorder.**

**BY**

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**Durban**

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## DECLARATION

This is to certify that the work is entirely my own and not of any other person, unless explicitly acknowledged (including citation of published and unpublished sources). The work has not previously been submitted in any form to the Durban University of Technology or to any other institution for assessment or for any other purpose.

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## **DEDICATION**

I dedicate this book to my son Siyanda Lwandile Nyoka. He was my inspiration every time I told myself I could not do it you were my reason for getting up and working hard to reach my dreams of becoming a qualified Homoeopathic doctor.

To my incredible mother, who showed me constant support even when times were tough. I have heard sayings that women are rocks (izimbokodo), you have proved it constantly. You are my rock who always gives me support when I cannot stand by myself and this accomplishment is dedicated to you. Your values, advice and education that you impressed upon me will never be forgotten.

To God Almighty, I would like to dedicate this accomplishment as my faith in him help me endure anything that I came across; for your constant blessings and abundant love, may you stay in my life forever and go with me in whatever the future holds for me.

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# **ABSTRACT**

## **Brief background**

According to Elliott Premenstrual Dysphoric Disorder (PMDD) was previously known as late luteal phase dysphoric disorder (LLPDD). Thielen states that PMDD is a severe, sometimes disabling extension of premenstrual syndrome (PMS). According to Thielen it causes extreme mood shifts that can disrupt work and damage relationships. Symptoms usually begin seven to 10 days before menses starts and continue for the first few days of menses. PMDD presents with the following emotional and behavioural symptoms: sadness or hopelessness, anxiety or tension, extreme moodiness and marked irritability or anger.

## **Methodology**

The number of people that took part in the study was 30 people who were between 18 and 35 years of age who qualify with the inclusion criteria for PMDD as stated by the Diagnostic and Statistical Manual of Mental Disorders 5<sup>th</sup> edition (DSM V) (2013) (Appendix E), had read the information letter (Appendix A), and signed the consent form (Appendix B). The sample was selected using non-probability convenience sampling. The number of people was randomly divided into two groups of 15 participants – treatment group and placebo group. The duration of the study was 3 months with 3 consultations in total; each consultation was within a week before their next expected menstruation cycle.

Measurement tools were the single item Visual Analogue Scale (VAS) (DSM IV 2000; Crichton 2001) (Appendix C) and the Kessler Psychological Distress Scale (K10) (KPD) (Andrews and Slade 2001) (Appendix D) which were applied in each consultation. Participants were evenly distributed between the treatment group and placebo group. All data collected was analysed using SPSS version 22.0. The research study took place at the Durban University of Technology (DUT) Homoeopathic Day Clinic (HDC) under the supervision of a qualified and registered homoeopath. Before the study commenced permission to conduct the study was requested and granted by all relevant stakeholders [Appendix F (a, b, c)].

## **Results**

The results of the study showed that there was no statistical significance between the two groups on both measurement tools. The traditional approach to reporting a result requires a statement of statistical significance. A p-value is generated from a test statistic. A significant result is indicated with " $p < 0.05$ ". It is noted that the differences observed per visit per scale were not statistically significant different. That is, the treatment and placebo groups showed similar results.

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## LIST OF ACRONYMS

<b>Acronym</b>	<b>Full Name</b>
Dr	Doctor
DSM	Diagnostic and Statistical Manual of Mental Disorders
DUT	Durban University of Technology
GAD	Generalised anxiety disorder
GIT	Gastrointestinal
GnRH	Gonadotrophin-releasing Hormone
HDC	Homoeopathic Day Clinic
KPD	Kessler Psychological Distress Scale
PMDD	Premenstrual Dysphoric Disorder
PMS	Premenstrual Syndrome
SSRI	Selective serotonin re-uptake inhibitor
VAS	Visual Analogue Scale

## OPERATIONAL DEFINITIONS

*Consultation*: a service provided by a physician whose opinion or advice regarding evaluation and management of a specific problem is requested (Schwalm 2006).

*Homoeopathy*: derived from the Greek words *homeos* and *pathos*, which mean 'similar suffering'. When a natural substance is given to a healthy individual, symptoms will arise and when that same substance is ingested by someone ill with similar symptoms its acts as a curative (Dancu 1996).

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

*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).

*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 effect*: the difference in outcome between a placebo treated group and an untreated control group in an unbiased experiment (Peters 2001).

*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.

*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 1996).

*Treatment group:* The group of subjects in a clinical trial who receive treatment that is specific for a given condition (Bloch 2002).

*Vital force:* the “spirit-like life force that enlivens the material organism as dynamis, governs without restriction and keeps all parts of the organism in admirable, harmonious, vital operation, as regards both feelings and functions, so that our indwelling, rational spirit can freely avail itself of this living, healthy instrument for the higher purposes of our existence” (O’Reilly 1996).

*Luteal phase:* The phase that starts on ovulation day, the day the egg is released from the egg follicle on the ovary. It can happen any time from day 7 to day 22. (Merck Manual 2008)

*Homoeopathic complex:* When more than two homoeopathic remedies are combined together prepared from different tincture, and those combined remedies are complementary remedies (Swayne 2000: 46).

*Treatment group:* The group of participants in the clinical study that is getting the medicated treatment



# **CHAPTER 1:ORIENTATION TO THE STUDY**

## **1.1 BACKGROUND TO THE STUDY**

According to the Diagnostic and Statistical Manual of Mental Disorders 5<sup>th</sup> edition (DSM V) (2013), the criteria for a patient to be diagnosed with pre-menstrual dysphoric disorder (PMDD) the patient must indicate to have at least five or more of the symptoms appearing in the DSM inclusion criteria with at least one related to emotional symptoms. Many research studies on PMDD disorder are being conducted as the aetiology that triggers PMDD is still unclear, but the majority of researchers agree that the baseline of the cause is psychiatric and it is a medical syndrome (Elliot 2002: 72). The monthly routine occurrence of symptoms links the disorder to a hormonal base disturbance.

Premenstrual syndrome (PMS) symptoms and PMDD symptoms can easily be misinterpreted in patients; but with PMDD the most obviously marked symptoms are emotional symptoms. The emotional symptoms in PMDD are more severe compared to physical symptoms such as breast tenderness (Grady-Weliky 2003: 433). The majority of young women (75%) experience the symptoms of premenstrual syndrome when they reach the stage of menstruation. PMS symptoms are not that intense compared to those of PMDD and patients can live with them with no distraction (Grady-Weliky 2003: 433).

## **1.2 PROBLEM STATEMENT**

The reported percentage of young women in their menstrual phase who are affected by the disorder and seek medical attention is 3% to 8%. Their symptoms are generally managed well and are under control (A.D.A.M Medical Encyclopaedia 2016). The number of women that are classified as having PMDD is very high but most of them do not report the problem until early in their 20s which as a result makes it difficult to manage the symptoms well because most women only get treatment years later in

their early stages of pre-menopausal when PMDD symptoms are converting to pre-menopausal symptoms (Grady-Weliky 2003: 433).

Murray and Lopez (1996: 1-23) suggested that with the lack of direct treatment of PMDD available, professional practitioners do not have much positive advice for their patients with regards to PMDD because the current treatment has severe side effects which can cause major setbacks to patients already suffering with PMDD. In 2001 when the World Health Organization with the World Bank were compiling reports to be published related to physical and mental disorders, no information on PMDD was included in the report despite the fact that the report specified 14 neuropsychiatric illness (Murray and Lopez 1996:1-2).

### **1.3 Aim of the study**

The aim of the study was to determine the efficacy of a homoeopathic complex treatment containing (*Sepia officinalis* 30CH, *Pulsatilla pratensis* 30CH, *Passiflora incarnata* 30CH, *Kalium phosphoricum* 30CH and *Natrium muriaticum* 30CH) in controlling PMDD.

## **1.4 OBJECTIVES**

### **1.4.1 Objective 1**

To determine the efficacy of a homoeopathic complex treatment compared to a placebo in terms of the single item visual analogue scale (VAS) (DSM IV 1995; Crichton, 2001) in the management of PMDD.

### **1.4.2 Objective 2**

To determine the efficacy of a homoeopathic complex treatment as compared to placebo in terms of the Kessler Psychological Distress Scale (K10) (KPD) (Andrews and Slade 2001) in the management of PMDD.

## **1.5 HYPOTHESES**

- Hypothesis 1: patients in the active group will show more statistical significance compared to the placebo group with regards to VAS.
- Hypothesis 2: patients in the active group will show more statistical significance compared to the placebo group with regards to KPD.
- Hypothesis 3: patients in the placebo group will not show statistical significance with regards to VAS.
- Hypothesis 4: patients in the placebo group will not show statistical significance with regards to KPD.

## **1.6 ASSUMPTIONS**

While conducting the study the following assumptions were made:

- In every consultation the participants were completing the measurement tools honestly and according to the way each individually experienced the symptoms.
- The participants were taking their medication as instructed not forgetting to take it and not just remembering when reminded by the researcher over telephone check-ups.
- The participants followed the instruction of how to store the homoeopathic medication.
- Participants did not have a change in lifestyle for the duration of the study.

## **1.7 THE SIGNIFICANCE OF THE STUDY**

The importance of the study is to determine if there is statistical significance in the treatment group the results will aid in the development of a PMDD treatment protocol. Grady-Weliky (2003: 433) states that women who are diagnosed with PMDD do not get help right away but only when the symptoms are very severe do they get medical help.

With regards to PMDD not enough studies have been conducted to prove the efficiency of homoeopathic clinical trials; more research needs to be done in this area.

Laister (2008) conducted a study on the effectiveness of homoeopathic simillimum in the management of premenstrual syndrome (PMS). The number of people who took part in the study consisted of women between the ages of 18 and 40 living in the greater Durban area. The people who took part were randomly divided into two groups (treatment and placebo). The intra-group analysis showed statistically important changes in the subgroups of water retention ( $p = .020$ ) and appetite changes ( $p = .010$ ) in the treatment group. The placebo group showed statistically important 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 was that there was no efficacy in the homoeopathic simillimum in the treatment of PMS. There were clinical changes noted by the people who took part during the study which suggested that more research into the treatment of PMS should be conducted. Studies with a larger number of people to take part over a longer period of time with daily outcome measures would give a better indication of the effectiveness of the homoeopathic simillimum on PMS.

# CHAPTER 2: LITERATURE REVIEW

## 2.1 INTRODUCTION: DEFINITION OF PMDD

Premenstrual Dysphoric Disorder (PMDD) is a condition characterized by depressed or labile mood, anxiety, irritability, anger, and other symptoms occurring exclusively during the 2 weeks preceding menses (Htay 2014). PMDD affects between 3% and 8% of women during the years when they are having menstrual periods. Premenstrual syndrome (PMS) refers to physical and emotional symptoms that occur in the one to two weeks before a woman's period. Symptoms often vary between women and resolve around the start of bleeding. Common symptoms include acne, tender breasts, bloating, feeling tired, irritability, and mood changes.

PMDD as described by DSM V (2013) is characterised by decreased daily functions, emotional and cognitive behavioural level. The presently known medical treatment for PMDD is antidepressants which may have various uncomfortable side effects and may cause withdrawal-like symptoms (Liades 2013).

## 2.2 THEORIES OF AETIOLOGY

According to the DSM-V (2013) PMDD is a psychiatric disorder and is classified as emotional related disorder. 5-Hydroxytryptamine (5-HT) is a hormone found in the brain, platelets, digestive tract, and pineal gland. It acts both as a neurotransmitter (a substance that nerves use to send messages to one another) and a vasoconstrictor (a substance that causes blood vessels to narrow). However, Elliott (2002) disagrees with the theory of PMDD being caused by hormonal imbalance, stating that PMDD symptoms start in the late luteal phase of menstruation which is when the levels of 5-Hydroxy tryptamine are reduced. Reduced 5-Hydroxy tryptamine causes irritability, dysphoria and carbohydrates cravings. Based on that he concluded that PMDD is rather caused by increased central nervous system sensitiveness to normal hormonal cycling which results in reduced levels of 5-Hydroxy

tryptamine. Other neurotransmitters are believed to also be the cause of PMDD (Elliott 2002).

### **2.2.1 Hormonal Imbalance**

#### **2.2.2 Oestrogen and progesterone imbalance**

When there is excess oestrogen in comparison to progesterone, the result is imbalanced hormones. ... Symptoms of depression, mood swings and anxiety due to the overbearing influence of oestrogen over progesterone, may become apparent and the bubbliest of women no longer the life of the party.

Segebladh et al. (2009) stated that the combination of oestrogen and progesterone given in high dosage to women with PMDD symptoms enhances the symptoms even further.

#### **2.2.3 Oestradiol**

Segebladh et al. (2009) conducted a clinical trial of patients with severe PMDD. Patients were given ethinylestradiol in combination with drospirenone which showed positive results in that the patient's symptoms improved.

#### **2.2.4 Nutritional and dietary deficiencies**

Sayegh et al. (1995) state that deficiency of carbohydrates, calcium and vitamin C may have an impact on aggravating the symptoms such as anxiety, depression, fatigue, irritability, mood swings, cramping and bloating.

## **2.3 EPIDEMIOLOGY**

According to (Hylan et al. 1999) 8% to 16% of menstruating age women have skipped work due to PMS related symptoms. PMDD on the other hand has a great impact on socio-economic aspects with the emotional symptoms it produces. Studies have been conducted to evaluate the lifestyle impairment of PMDD/PMS with the results being compared to other emotional related disorder and the impact they have on socio-economic aspects.

## **2.4 PMDD signs and symptoms**

The symptoms of PMDD are almost the same as those of PMS, although they are generally more drastic, exhausting and include at least one mood related symptom (Elliott 2002; DSM V 2013). Symptoms appear a week before menses during the late luteal phase and usually subside within a few days after menstruation has commenced. The main symptoms which can be exhausting include feelings of sadness or despair, thoughts of suicide, feelings of tension or anxiety, panic attacks, mood swings or frequent crying, irritability or anger that affects other people, lack of interest in daily activity and relationship, trouble thinking, tiredness or low energy levels, food cravings especially carbohydrates, trouble sleeping and physical symptoms such as bloating, breast tenderness, headaches and joint pains (Elliott, 2002). Llewellyn-Jones et al. (1999) add the symptom of hot flushes which is a sudden heat sensation that starts around the head and extends down the rest of the body.

Table 2.1 lists the physical, mental and behavioural symptoms presented by PMS and PMDD.

**Table 2.1: physical, psychological and behavioural symptoms of PMS and PMDD**

<b>Physical</b>	<b>Psychological and Behavioural</b>
Abdominal bloating	Anger, irritability
Body aches	Anxiety
Breast tenderness and/or fullness cravings)	Changes in appetite (overeating or food
Cramps, abdominal pain	Changes in libido
Fatigue	Decreased concentration
Headaches	Depressed mood
Nausea	Feeling out of control
Swelling of extremities	Mood swings
Weight gain	Poor sleep or increased need for sleep
	Tension
	Withdrawal from usual activities"

Source: Adapted from the American Family Physician (2011) internet.

## **2.5 THE DIAGNOSIS OF PMDD**

DSM–5 is a manual for assessment and diagnosis of mental disorders and does not include information or guidelines for treatment of any disorder. That said, determining an accurate diagnosis is the first step toward being able to appropriately treat any medical condition, and mental disorders are no exception (American Psychiatric Association 2013). For confirmation of PMDD five or above of the mentioned symptoms must be present to diagnose PMDD including one mood related symptom (Storck 2014; Elliott 2002; DSM V 2013) (Table 2.2). Elliott (2002: 73-74) also comments on the importance of taking note that these symptoms start during the late luteal phase of menstruation because that's the hallmark of PMDD symptoms.

**Table 2.2: Diagnostic criteria for PMDD according to DSM V (2013)**



<b>Table 2: Diagnostic Research Criteria for Premenstrual Dysphoric Disorder</b>	<b>YES/NO</b>
A. In most menstrual cycles during the past year, five (or more) of the following symptoms occurred during the final week before the onset of menses, started to improve within a few days after the onset of menses, and were minimal or absent in the week post menses, with at least one of the symptoms being either (1), (2), (3), or (4):	
(1) marked affective liability (e.g., mood swings; feeling suddenly sad or tearful or increased sensitivity to rejection) (2) marked irritability or anger or increased interpersonal conflicts (3) markedly depressed mood, feelings of hopelessness, or self-deprecating thoughts (4) marked anxiety, tension, feelings of being "keyed up" or "on edge" (5) decreased interest in usual activities (e.g., work, school, friends, hobbies) (6) subjective sense of difficulty in concentration (7) lethargy, easy fatigability, or marked lack of energy (8) marked change in appetite, overeating, or specific food cravings (9) hypersomnia or insomnia (10) a subjective sense of being overwhelmed or out of control (11) other physical symptoms such as breast tenderness or swelling, joint or muscle pain, a sensation of "bloating," weight gain	
B. The symptoms are associated with clinically significant distress or interferences with work, school, usual social activities or relationships with others (e.g. avoidance of social activities, decreased productivity and efficiency at work, school or home).	
C. The disturbance is not merely an exacerbation of the symptoms of another disorder, such as major Depressive disorder, panic disorder, dysthymic disorder, or a personality disorder (although it may be superimposed on any of these disorders).	
D. The symptoms are not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication or other treatment) or a general medical condition (e.g., hyperthyroidism).	

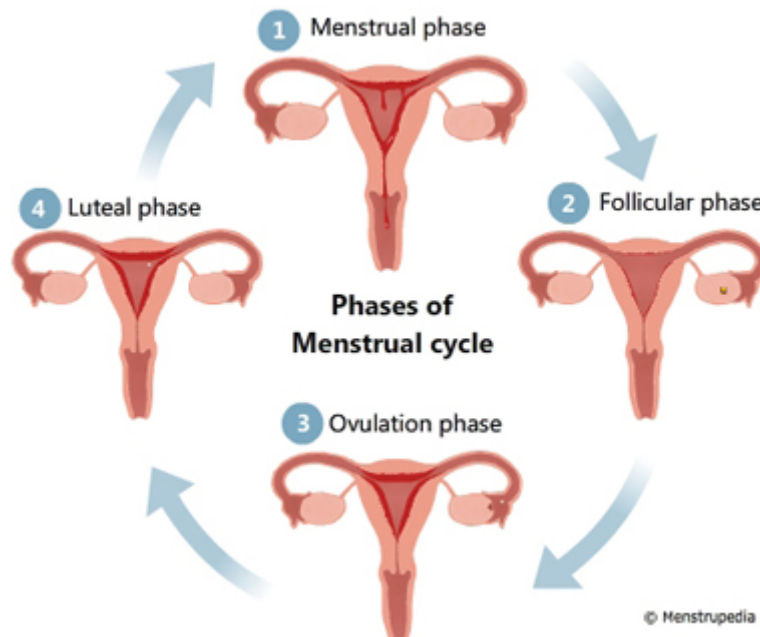
Source: Adapted from Diagnostic and Statistical Manual of Mental Disorders version 5, 2013 internet.

### **2.5.1 NORMAL MENSTRUAL CYCLE**

In the Merck manual (2011) it is stated that the menstruation cycle starts on the first day of menstruation when the bleeding commences and the average days for most women the cycle is 28 days (Figure 2.5.1). The whole cycle can be classified into 4 stages labelled:

- Menstruation stage (from day 1-5)
- Follicular stage (from day 1-13)
- Ovulation stage (day 14)

- Luteal stage (from day 15-28)

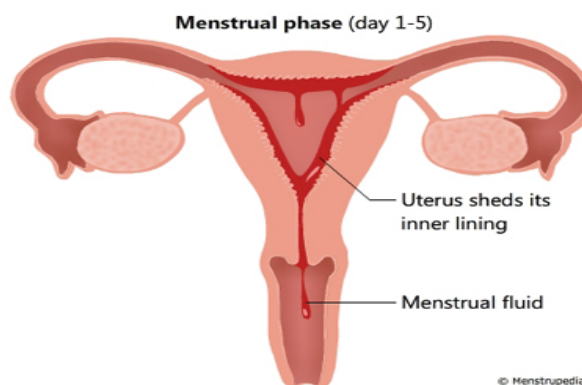


**Figure 2.5.1. Stages of menstruation**

Source: Adapted from Google Images 2016

## 2.5.2 Menstruation stage

The following happens during the time the uterus scrap its inner lining of soft tissue and blood vessels this appears in a form of menstrual fluid (Figure 2.5.2). Abdominal cramps may be experienced.

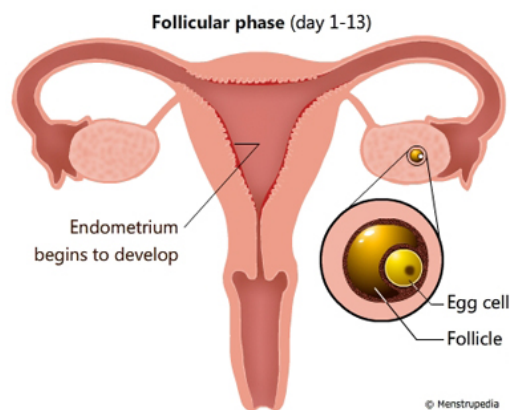


**Figure 2.5.2 : Menstruation stage**

Source: Adapted from Google Images 2016

### 2.5.3 Follicular stage

In this stage the pituitary gland secretes hormones that stimulate the egg cells in the ovaries to grow (Figure 2.5.3). One of these eggs mature into a sac like structure called a follicle taking 13 days. While this is happening, the follicle secretes a hormone that stimulates the uterus to develop a lining of blood vessels and soft tissue called the endometrium.

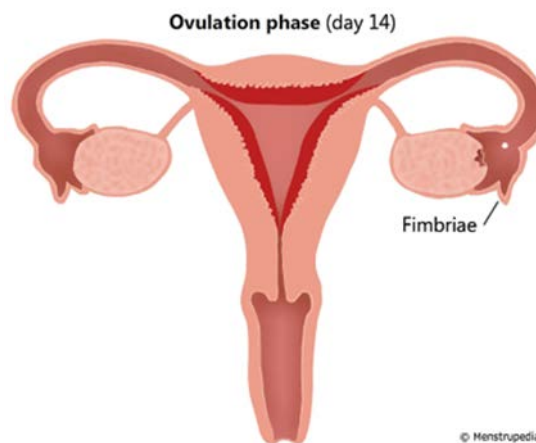


**Figure 2.5.3.: Follicular stage**

Source: Adapted from Google Images 2016

### 2.5.4 Ovulation stage

On day 14 of the cycle the pituitary gland secretes a hormone that causes the ovary to release the matured egg into the fallopian tube (Figure 2.5.4).



### Figure 2.5.4.: Ovulation stage

Source: Adapted from Google Images 2016

## 2.5.5 Luteal stage

This stage starts on the day ovulation, when the egg is released from the egg follicle (Figure 2.5.5). Some women have red spotting or lower pelvic pain or discomfort during this phase. This is the stage when PMDD symptoms arise.

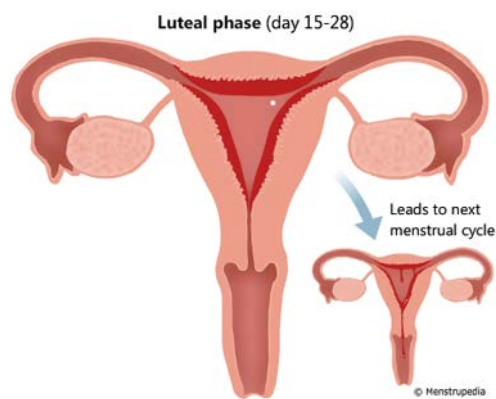


Figure 2.5.5.: Luteal stage

Source: Adapted from Google Images 2016

## 2.6 DIFFERENTIAL DIAGNOSIS

### 2.6.1 Cyclic pelvic pain

Cyclic pelvic pain is a common gynaecological problem caused by relatively few disease. Premenstrual syndrome can be a diagnosis (KN Muse 1990).

### 2.6.2 Dysmenorrhoea

Dysmenorrhoea has a high prevalence rate of 90%. It is characterised by cramping pains in the lower abdomen, with the pains rated from mild to severe (Coco 1999.)

### **2.6.3 Endometriosis**

According to Giudice, Tazuke and Swiersz (1998), endometriosis is defined as stromal cells that are found in the abdominopelvic area which are not in their original place. It occurs in 10% of women in their reproductive age.

### **2.6.4 Affective disorders/ mood disorders**

#### **2.6.5 Depression**

Destruction to the normal lifestyle the mind is overwhelmed with thoughts of sorrow. According to Mayberg (2002: 193-207) states that it is the adaptive and maladaptive functional interactions.

#### **2.6.6 Dysthymic disorder**

Chronic depression with slow improvement patients feel exhausted on all levels emotionally, physical and mental with high risk of relapsing if any improvement shown by a patient (Am J Psychiatry, 2006:872-880)

## **2.7 ASSESSMENT TOOLS**

### **2.7.1 Visual Analogue Scale)**

A Visual Analogue Scale (VAS) (Appendix C) is a measurement instrument that tries to measure a characteristic or attitude that is believed to range across a continuum of

values and cannot easily be directly measured. For example, the amount of pain that a patient feels ranges across a continuum from none to an extreme amount of pain. From the patient's perspective, this spectrum appears continuous i.e. their pain does not take discrete jumps, as a categorization of none, mild, moderate and severe would suggest. It was to capture this idea of an underlying continuum that the VAS was devised.

Operationally a VAS is usually a horizontal line of 100 mm. As such an assessment is clearly highly subjective; these scales are of most value when looking at change within individuals (Crichton, 2001)

Steiner et al. (1999) conducted a study on PMS using VAS as a measurement tool and concluded that VAS proved to be a low burden to the patient, reliable, valid and sensitive to change. Many studies have used this scale effectively (for example Berger et al. 1999; Bodian et al. 2001; Teleman 2005; Ramoupi 2012; Price 2012).

### **2.7.2 Kessler Psychological Distress Scale (K10)**

Kessler Psychological Distress Scale (K10) (KPD) is a 10 questionnaire intended to yield a global measure of distress based on questions about anxiety and depressive symptoms that a person has experienced in the most recent 4-week period. The KPD scale depend on the patient self-report measure to collect data information on the patient's current condition and to establish a productive dialogue (Andrews and Slade, 2001).

## **2.8 CONVENTIONAL TREATMENT**

### **2.8.1 Medical treatment for PMDD**

Nordqvist (2018) states that antidepressants are medications that can help relieve symptoms of depression, social anxiety disorder, anxiety disorders, seasonal affective

disorder, and dysthymia, or mild chronic depression, as well as other conditions. They aim to correct chemical imbalances of neurotransmitters in the brain that are believed to be responsible for changes in mood and behaviour. Antidepressants were first developed in the 1950s. Their use has become progressively more common in the last 20 years.

The currently used medical treatment for PMDD which is antidepressants have numerous unpleasant side effects which may cause withdrawal-like symptoms (Iliades, 2013). According to Katz (1995), homoeopathy can be used to treat PMS, without the potential unwanted effects of hormonal treatment. Iliades (2013) states that the modalities of treatments that exist for the treatment of PMDD are mainly pharmacologic interventions such as antidepressant and anxiolytic medications. However according to Bhatia and Bhatia (2002), pharmacologic interventions have numerous unpleasant side effects. Homoeopathy has a different approach to conventional allopathic therapies with regards to health, disease, treatment and management of patients. The highest ideal of cure is a rapid, gentle and permanent restoration of health, or removal and annihilation of the disease in the shortest, most reliable and most harmless way.

### **2.8.2 Selective serotonin reuptake inhibitor (SSRI)**

Citalopram is a selective serotonin reuptake inhibitor. Serotonin is a neurotransmitter which acts as a pathway for chemicals between cells in the brain. Increasing the amount of serotonin in the brain results in improvement of symptoms related to depression. For PMDD patients it is given to lower the symptoms of depression hopelessness and feeling worthless.

About 70% of women who have PMS/PMDD symptoms experience a positive change after using sertraline, fluoxetine, paroxetine and citalopram which all belong to the selective serotonin reuptake inhibitors. The medication must be administered a week before menstruation commences. The results are seen within 24-48 hours of administration (Elliott, 2002: 73).

The common side effects related to citalopram are nausea, dry mouth, loss of appetite, fatigue, sweating and drowsiness. Citalopram is best taken at intervals rather than as a continuous dosage (Wikander et al. 1998).

### **2.8.3 Gonadotropin-releasing hormone agonist**

Gonadotropin-releasing hormone has proven to be useful in management of PMDD symptoms. (Elliott 2002). According to Elliott (2002), PMS/PMDD symptoms are associated with the hypothalamic-pituitary gonadal axis and produces its effect regarding PMDD by decreasing secretion of follicle stimulating hormone and luteinizing hormone (Elliott 2002:73). Despite being useful in treatment of PMDD symptoms it has been proven that gonadotropin-releasing hormone also produce side effects such as hot flushes, vaginal dryness, depression and muscle aches with headaches (Muse et al. 1984; Mortola 1993; Brown et al. 1994).

### **2.8.4 Danazol**

This is an androgen synthetic drug that is used primarily in the treatment of endometriosis. It decreases the amount of hormones produced by the ovaries. Danazol treatment is used to relieve the irritability, anxiety, lethargy, increased appetite, headaches and breast tenderness which are some of the symptoms present in patients with PMDD. Danazol is an androgen similar to testosterone. For the treatment of endometriosis and fibrocystic breast disease, it works by decreasing the amount of hormones made by the ovaries. These hormones usually make the conditions worse (Dreyer A.C et.al 2013).

## **2.9 Other treatments for PMDD**

### **2.9.1 Oral contraceptives**

A combined low dose of drospirenone and ethinyl estradiol known as Drospirenone (Angeliq®) showed a decrease in PMDD symptoms (Parsey and Pong 2000)



### **2.9.2 Herbal medicine**

According to Niederhofer (2009), phytotherapeutics such as *Passiflora incarnata*, *Matricaria chamomilla*, *Humulus lupulus*, *Ginkgo biloba*, *Melissa officinalis* and *Valeriana officinalis* are capable of decreasing PMDD symptoms and improve the lifestyle of patient with mood and hormonal disorders. *St John's Wort* increases the level of serotonin in a dosage of 900mg daily (Ravindran et al. 2007)

### **2.9.3 Non-pharmacological treatment**

Carbohydrate craving is a symptom of PMDD which is the result of the brain needing more tryptophan which is a precursor of serotonin (Elliott 2002: 74). Therefore, intake of carbohydrate complex can be useful. Exercise helps increase endogenous endorphins and cognitive and relaxation therapy helps patients cope with the symptoms (Elliott 2002: 74).

### **2.9.4 Vitamin and mineral supplements**

Other treatment that can be considered for management of PMDD symptoms intake of calcium carbonate which showed some improvement when it was used, with 48% of patients showing improvement. Magnesium supplements improve PMDD symptoms (Elliott 2002). Vitamin B6 (also known as pyridoxine) improves water retention.

## **2.10 HOMOEOPATHIC PHILOSOPHY AND APPROACH TO THE CONDITION**

Homoeopathy is the soft, deeply-healing system of medicine founded by Samuel Hahnemann in the early 19th century. Homoeopathy uses healing substances so dilute that they do not indicate any uncomfortable side effects like conventional pharmaceuticals. Conventional pharmaceuticals can suppress symptoms which then can later reoccur often on a deeper level. Homoeopathy heals patients from the inside

out. It removes the underlying emotional or mental stress of chronic disease first, and then moves the illness out of the body. Homoeopathy does not cause side effects and promotes the quality of life as it heals (De Schepper 2001).

According to Kent (2009) homoeopathy is an energy medicine, working with the body's own healing energy to strengthen it using remedies that are safe, non-toxic and totally individualised to the patient for both acute and chronic illnesses. Homoeopathy treats the whole person: emotional, mental and spiritual as well as physical. A well-chosen homoeopathic remedy brings about a profound sense of well-being before it even begins to cure the symptoms.

A person's individual healing energy affects the cure. It does not create resistance but uses extremely small doses of natural substances to stimulate the body's innate healing powers. Homoeopathic remedies are non-toxic and non-addictive (Lockie and Geddes 2005). According to Katz (1995), homoeopathy can be used to manage PMS without the potential uncomfortable effects of hormonal treatment. Katz (1995) and Muse (1992) further state that currently the conventional hormonal approaches to PMS involve treatment with oral contraceptive pills, oestradiol patches or gonadotrophin-releasing hormone (GnHR) analogues. Menkes et al. (1992) concur with Katz (1995) and Muse (1992), further adding that selective serotonin release inhibitors have been used to treat the emotional symptoms of PMS.

Homoeopathy is a complete range of medicine developed by Dr Hahnemann (1755-1843) based on the principle of "let likes cure likes". The homoeopathic approach is not only to treat a person for their physical complaints but to also consider their mental and emotional states as pivotal components in the healing and treatment process as well. Homoeopathic treatment differs from the more conventional forms of medicine in such a way that it is highly individualised and holistic (Kent, 2009).

### **2.10.1 The homoeopathic complex review**

### **2.10.2 Homoeopathic complex**

The homoeopathic complex treatment contains the following remedies: *Sepia officinalis* 30CH, *Pulsatilla pratensis* 30CH, *Passiflora incarnata* 30CH, *Kalium phosphoricum* 30CH and *Natrum muriaticum* 30CH (Elliott 2002).

These remedies are chosen for their indications related to PMDD characteristic symptoms. Farrington (2014) states that:

#### **2.10.3 *Sepia officinalis***

The remedy acts especially on pubescence, the critical period of life and has sensitivity to all impressions. It is also indicated for hormonal imbalances and suppressions.

#### **2.10.4 *Pulsatilla pratensis***

The disposition and mental state are the chief guiding symptoms to the selection of *Pulsatilla pratensis*. It is pre-eminently a female remedy, especially for mild, gentle, yielding disposition. Sad, crying readily; weeps when talking; changeable, contradictory. The patient seeks the open air; always feels better there, even though he/she is chilly. Mucous membranes are all affected. Discharges are thick, bland, and yellowish-green in colour. This often is indicated after abuse of iron tonics, and after badly-managed measles. Symptoms are ever changing. Thirstless, peevish and chilly. Have great sensitiveness and want the head high. Feels uncomfortable with using only one pillow. Lies with hands above head. (Boericke 1999.)

Mind: weeps easily. Timid, irresolute. Fears to be alone in evening, dark, ghosts. Likes sympathy. Children like fuss and caresses. Easily discouraged. Morbid dread of the opposite sex. Religious melancholy. Given to extremes of pleasure and pain. Highly emotional. Mentally, an April day. (Boericke 1999.)

#### **2.10.5 *Passiflora incarnata***

*Passiflora incarnata* has an effect on the nervous system and is used for sleep problems (insomnia), gastrointestinal (GI) upset related to anxiety or nervousness, generalized anxiety disorder (GAD), and relieving symptoms related to narcotic drug withdrawal. *Passiflora incarnata* is also used for seizures, hysteria, asthma, symptoms of menopause, attention deficit-hyperactivity disorder, nervousness and excitability, palpitations, irregular heartbeat, high blood pressure, fibromyalgia, and pain relief (Vermeulen 2001). According to Ashpari (2014), *Passiflora incarnata* boosts the brain's levels of a chemical called gamma-amino butyric acid (GABA), which lowers the brain activity. As such, it shows potential as a good sleep aid.

### **2.10.6 *Kalium phosphoricum***

*Kalium phosphoricum* is one of the greatest nerve remedies with a marked disturbance of the sympathetic nervous system. Mental and physical depression with irritability, anxiety, fatigue and restlessness before and during menses are improved by this remedy (Vermeulen 2001). Boericke (1999) states that *Kalium phosphoricum* is one of the greatest nerve remedies. Prostration. Weak and tired. Especially adapted to the young. Marked disturbance of the sympathetic nervous system. Conditions arising from want of nerve power, neurasthenia, mental and physical depression. The causes are usually excitement, overwork and worry. It corresponds to states of decay, gangrenous conditions. In these two directions it has won many clinical laurels. Remember it in the treatment of suspected malignant tumours. After removal of cancer when in the healing process skin is drawn tight over the wound. Delayed labour.

### **2.10.7 *Natrum muriaticum***

Characteristics are ill effects of grief, fright, anger, depression and excessive sadness before and during menses which is worse for consolation. Gloomy thoughts, recalls insults long since suffered (Murphy 2003). Vermeulen (2001) further states that there is sadness, reserved, and company distresses, worse before menses. Easily angered and inspires revenge. Wants to be alone to cry. Tears and laughter.

According to Yakir et al. (2001) homoeopathy is highly controversial, mainly because of the poor understanding of its mode of action, and because of the few number of controlled clinical trials it is difficult to assess its efficacy. However; in a randomised controlled double-blind clinical pilot study by Yakir et al. (2001) on the effects of homoeopathic treatment in women between the ages of 20 to 48 suffering from PMS, improvement of more than 30% was found in 90% of women in the homoeopathic treatment group and in 37.5% of the control group. The efficacy of the homoeopathic treatment over placebo can thus be estimated as 59%. Another case series study by Danno et al. (2013) on homoeopathic treatment of PMS showed that homoeopathic medicines appeared to be effective at reducing PMS symptoms. These studies confirm the place of homoeopathic medicines in the management of women with PMS.

### **2.11 PLACEBO EFFECT**

Majority of clinical studies use the placebo. According to the Oxford English Dictionary (2003), a placebo is an inert or innocuous substance used in controlled experiments testing the efficacy of another substance. Research has shown that the expectations of patients can influence their healing process and since they expect their medication to work, the placebo may have therapeutic effect. Therefore, during a clinical study, active medication is tested against a control receiving a placebo to make sure that any positive results take into account this placebo response, and for any medication or drug to be deemed effective the positive results shown by the treatment group must far outweigh the placebo group (Lockie and Geddis 2005).

### **2.12 SIGNIFICANCE**

PMDD's effect is growing tremendously and many women are affected by the disorder, but due to a lack of information available to clarify what they are experiencing, this has resulted in women having to learn to live with these severe symptoms affecting their lifestyles (Hylan et al. 1999). The current treatment used to manage the symptoms

produces severe side effects. Homoeopathic medication does not cause side effects and enhances the quality of life as it heals (De Schepper 2001).

According to Katz (1995), homoeopathy is documented as a therapy that can be used to treat hormonal disorders and premenstrual symptoms without the potential of unwanted effects of hormonal treatment. At the Royal London Homoeopathic Hospital's (RLHH) women's clinic, approximately 40% of patients presented with some form of premenstrual discomfort, ranging from severe and incapacitating to mild symptoms. Of these patients, 85% reported some relief of their symptoms after taking homoeopathic remedies. Most patients experienced an increased sense of wellbeing along with alleviation of the PMS, without suffering toxic side-effects. Yakir et al. (2001) state that homoeopathy is highly mis-understood by many clinicians, mainly because of the poor understanding of its mode of action, and because of the limited number of controlled clinical trials it is difficult to assess its efficacy. However; in a randomised controlled double-blind clinical pilot study, Yakir et al. (2001) found that homoeopathic treatment of women between the ages of 20-48 suffering from PMS resulted in an improvement of more than 30% in 90% of women in the homoeopathic treatment group and in 37.5% in the control group.

## **CHAPTER 3: RESEARCH METHODOLOGY**

### **3.1 INTRODUCTION**

The concept of the study was explained in detail including the methodology that was the baseline followed while conducting the study. This chapter outlines the procedure followed during the study.

### **3.2 RESEARCH DESIGN**

The study was a randomised double-blind placebo controlled clinical trial. A double-blind trial is a trial where neither the researchers nor the patients know what they are getting. The computer gives each patient a code number. And the code numbers are then allocated to the treatment groups. Your treatment arrives with your code number on it.

### **3.3 SETTING**

The study was conducted at the Durban University of Technology (DUT), Homoeopathic Day Clinic (HDC) under the supervision of a qualified and registered homoeopath during clinic hours.

### **3.4 SAMPLING PROCESS**

Thirty people were recruited to participate in the study. The 30 consenting females were between the ages 18 to 35 years of age from Durban, KwaZulu-Natal province, who qualify with the inclusion criteria according to the DSM V (2013). The 30 people were randomly and evenly distributed between the treatment group and control/placebo group. A non-probability convenience sampling method was used. The sample size was 30 consenting female participants with PMDD. Based on previous Homoeopathic clinical trial studies done at DUT by Megan Jones (2009), Carla Swan (2003), Shada Ismail (2003), Julia Elderidge (2000), and Maureen Dos Ramos (2000)

among the few, which have used 30 participants in their trial, a sample size of 30 will be statistically significant.

### **3.4.1 Randomisation**

Randomisation was done by an independent qualified and registered homoeopath within the Department of Homoeopathy nominated by the Department of Homoeopathy Research Committee (DRC). A Randomisation table was drawn from 1-30 (15 participants were part of the control group and 15 participants part of the experimental group) by the researcher and submitted to the above-mentioned independent person by the supervisor who was not blinded. The independent person then performed randomisation by assigning the random numbers from random number tables (1-30) to the treatment conditions (with 15 participants in experimental group and 13 participants in control group).

### **3.4.2 Inclusion Criteria:**

Participants who met the inclusion criteria for PMDD as stated by DSM V (2013) (Appendix E) were accepted as part of the study.

### **3.4.3 Exclusion criteria**

a) The disturbance was not merely an exacerbation of the symptoms of another disorder, such as major depressive disorder, panic disorder, dysthymic disorder, or a personality disorder (although it may be superimposed on any of these disorders).

b) The symptoms were not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication or other treatment) or a general medical condition (e.g., hyperthyroidism).

- Person who did not meet the inclusion criteria for PMDD as stated by DSM V (2013).
- Person that were not females.
- Person that was not in the required age group which was between the ages 18 to 35 years.



- Person who did not living around Durban, KwaZulu-Natal due to short duration of the study far participant would not make it on time.
- Person who were on any treatment for PMDD.
- Person that had no co-existing chronic medical or mental condition/s.
- Person that was pregnant or intending to conceive in the course of the study.
- Person that had surgery in the past six weeks.
- Person that were on any recreational drugs.
- Person on contraceptive medication.
- Person that had irregular menstrual periods.

These criteria ensured the exclusion of individuals who had extraneous factors which may have had an impact on the study. A clinician was present on site as per normal standard operating protocol for all clinical studies and research studies within the department.

### **3.5 Data collection process**

#### **3.5.1 The procedure**

##### **Consultation details**

The period of the study was 12 weeks (3 months). There were 3 consultations in which the measurement tools were applied in each consult with the participant.

The first consultation was regarded as baseline, thereafter the participants were seen for two more consultations which were after each cycle of menses. The participants were given treatment according to the randomisation list.

##### **Consultation one: (at the set/ start of menstruation)**

- **Step one:** The participants were fully told about about the study. They were given the information letter (Appendix A), participants had a chance to ask questions about the study.
- **Step two:** The participants then signed the consent form (Appendix B) on agreeing to participate on the study.

- **Step three:** On both the information letter and consent form there was information about participants not being forced to participate in the study and that there was no remuneration for taking part in the study and that participants may withdraw at any time during the study without any prejudice and lastly that there was going to be a samples of body fluid required specifically for the research which would not be required in the case of ordinary treatment (urine sample for pregnancy testing to exclude pregnant participants).
- **Step four:** The researcher applied the measurement tools (Appendix C & D) if the participant met the inclusion criteria (Appendix E) and had signed the consent form (Appendix B).
- **Step five:** A detailed case history was taken (Appendix J).
- **Step six:** Full physical examination was performed and a SOAPE note was completed by the researcher (Appendix K) and signed by the clinician.
- **Step Seven:** Medication was dispensed according to the randomisation list drawn by an independent person (one group received an active oral homoeopathic complex and the other inactive oral drops).
- **Step eight:** The participants proceeded to the Clinic reception area where the dispenser on duty dispensed a fully labelled allocated medication with instruction on when and how to take homoeopathic medication details (Appendix L).

#### **Consultation two:**

- **Step nine:** The researcher called the participants on a weekly basis to investigate if the participants were still taking their medication as instructed and to remind the participant of their next consultation a week before their next expected period/menses.
- **Step ten:** The researcher applied the measurement tools (Appendix A & B).
- **Step 11:** A detailed follow up case was taken (Appendix M).
- **Step 12:** Repeated step six to step eight from consultation one.

#### **Consultation three:**

- **Step 13:** The researcher called the participants to remind them of their next consultation – a week before their next expected period/menses.
- **Step 14:** The researcher applied the measurement tools (Appendix A & B).
- **Step 15:** A detailed follow up case was taken (Appendix M).
- There was no medication prescribed on the final follow up.
- The participants were thanked for their participation in the study and were informed that they were welcome for further treatment at the HDC should they be in need of medical attention and those in the placebo group received free treatment at the end of the research study.

### **3.6 Data analysis**

Descriptive statistics was employed in the form of tables and graphs. Measures of central tendency and dispersion was calculated where applicable. Inferential tests included: chi-square goodness of fit test, repeated measures ANOVA, t-tests. Where conditions were not met, equivalent non-parametric tests were applied. A statistician was consulted to assist with determining the sample size and tests for analysing data (See letter from statistician Appendix G).

### **3.7 ETHICAL CONSIDERATIONS**

The study was carried out according to the approved DUT protocol and standards. After participants were informed of all the known possible risks involved, full permission was attained from the participant. The participants participated in the study voluntarily and there were not forced to be part on the study by the researcher or the supervisors of the study or DUT. The study was always under constant supervision by the supervisors and the clinicians on duty at the HDC.

Permission to use all the scales was given by the rightful owners (Appendix N). All the information collected from people who took place in the study was handled with strictest confidence. Only the supervisors, the researcher and the clinicians had access to the participants' files. Participants' confidential information that was not

relevant to the study were not mentioned in public, all data was coded in numbers and password protected. The data collected was stored in a safe place with the department of homoeopathy and will be destroyed appropriately after five years as per DUT regulations.

Before the study started, letters requesting the use of the DUT facility (Homoeopathic Day Clinic and dispensary), students and staff were sent from the relevant people (Appendix F). Permission to use a DUT facility, students and staff were requested from the Research and Postgraduate Support Director-Professor Sibusiso Moyo, once permission was granted the study commenced.

The study was guided by the research problem and after the data was collected and organised, the collected data was interpreted to give meaning to the data which led to a resolution of the problem, thus confirming / not confirming the hypotheses and providing an answer to a question. The outcome of the research was to determine the efficacy of a homoeopathic complex in the management of PMDD using the measurement tools VAS and KPD and to compare the results with the placebo group results using the same measurement tools. In the next chapter the researcher analyses the data by tabulating it and using tables and pie charts to present the data.

# CHAPTER 4: PRESENTATION OF RESULTS

## 4.1 INTRODUCTION

This chapter presents the results and discusses the findings obtained from the two questionnaires in this study. The questionnaires were the primary tools that were used to collect data. The data collected from the responses was analysed with SPSS version 22.0. The results will be presented by means of descriptive statistics in the form of graphs, cross tabulations and other figures for the quantitative data that was collected. Inferential techniques include the use of correlations and chi square test values, which are interpreted using the *p*-values.

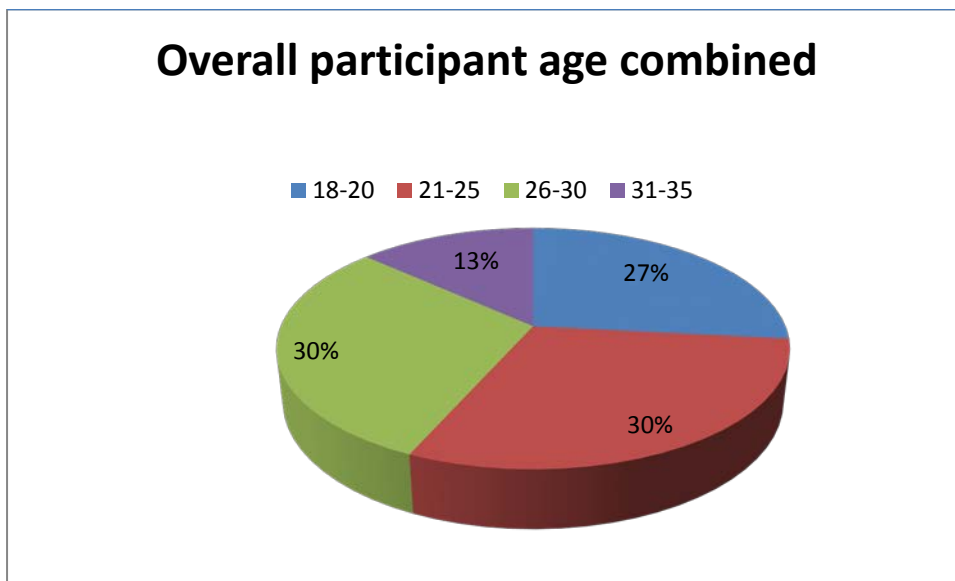
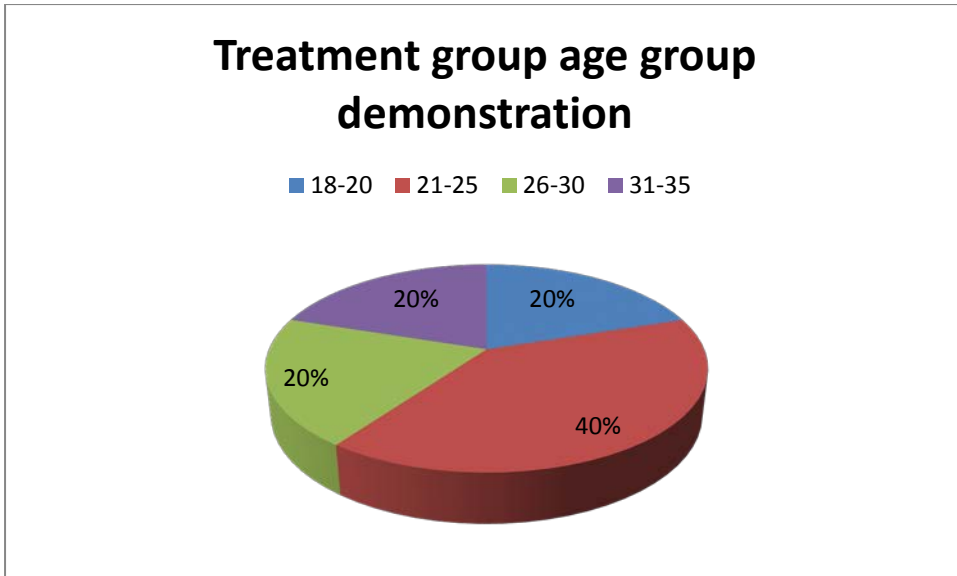


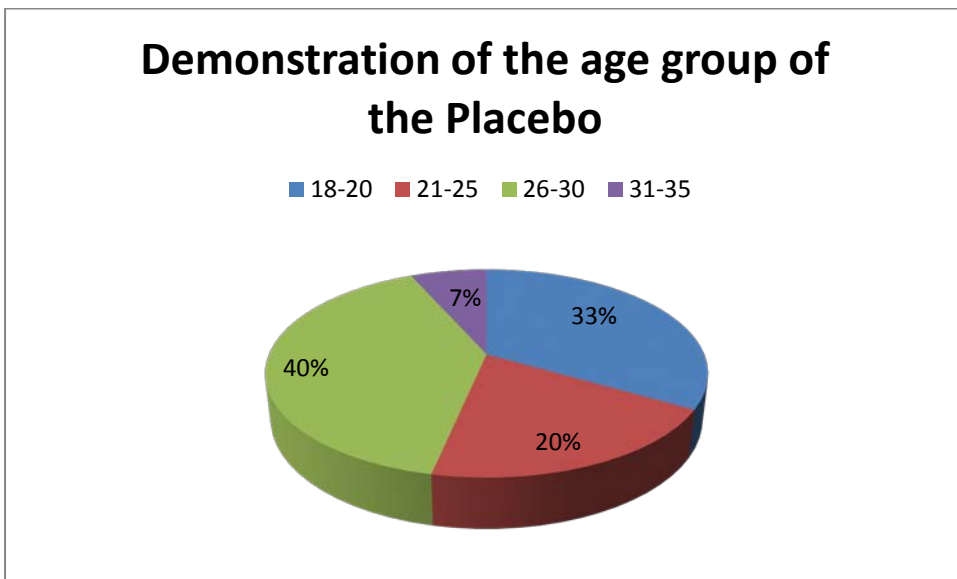
Figure 4.1: Overall participant age

Figure 4.1 shows the overall age of the treatment and placebo group.



**Figure 4.2: Treatment group age**

Figure 4.2 shows the age of the treatment group.



**Figure 4.3: Placebo group age**

Figure 4.3 shows the age of the placebo group.

## 4.2 THE SAMPLE

In total, 30 participants were recruited to participate in the study and two groups were formed with 15 in each group. The participants were randomly distributed into the two groups.

### 4.2.1 The research instruments

The VAS research instrument consisted of five items, with a level of measurement at an ordinal level. The KPD had ten questions based on ordinal data.

### 4.3 RELIABILITY STATISTICS

The two most important aspects of precision are reliability and validity. Reliability is computed by taking several measurements on the same subjects. A reliability coefficient of 0.70 or higher is considered as “acceptable”. The tables below reflect the Cronbach’s alpha score for all the items that constituted the questionnaires.

**Table 4.1: Cronbach’s alpha for VAS**

Reliability Statistics	
Cronbach's Alpha	N of Items
.628	18

**Table 4.2: Cronbach’s alpha for KPD**

Reliability Statistics	
Cronbach's Alpha	N of Items
.859	30

The reliability score for the VAS is slightly below the acceptable score (Table 4.1), but the KPD exceeds the recommended Cronbach’s alpha value (Table 4.2). This indicates a degree of acceptable, consistent scoring for these sections of the research.

### 4.4 ANALYSIS

The sections that follows analyses the scoring patterns of the respondents per visit per variable. The mean and median values and frequency ratings across visits are used for comparative purposes.

V =VAS and numerical is for the number of consultations. K= Kessler scale and numerical is for the number of consultations

Table 4.3: Means of comparison

		31			
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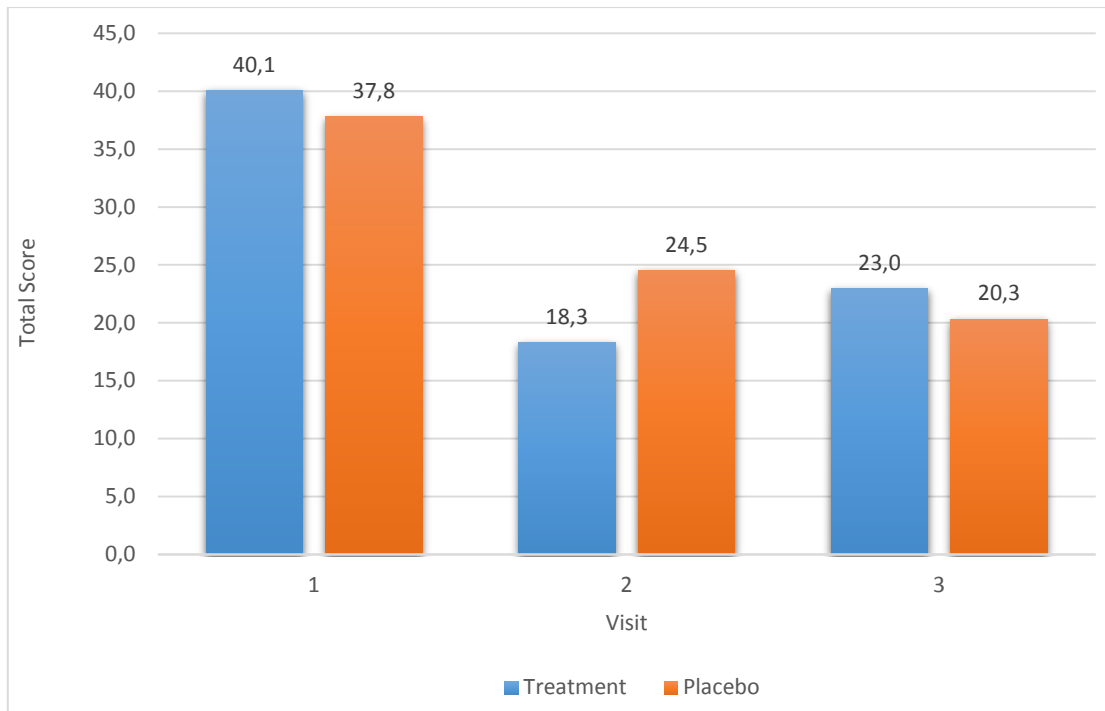
Group		V1	V2	V3	K1	K2	K3
Treatment	N	15	15	15	15	15	15
	Mean	40.1	18.3	23.0	30.4	21.1	18.5
	Median	40.0	19.0	23.0	29.0	19.0	17.0
	Std. Deviation	6.9	9.8	11.8	7.7	8.1	6.5
Placebo	N	15	15	15	15	15	15
	Mean	37.8	24.5	20.3	29.8	18.7	20.1
	Median	35.0	21.0	19.0	29.0	18.0	17.0
	Std. Deviation	9.0	7.1	6.4	7.2	5.2	8.2

Table 4.3 shows that the treatment group response demonstrated little difference when compared to the placebo group's response. The standard deviation outcome of the treatment group shows only slight improvement of symptoms and these improvements were not noted on all the visits. The treatment group was expected to demonstrate a greater improvement.

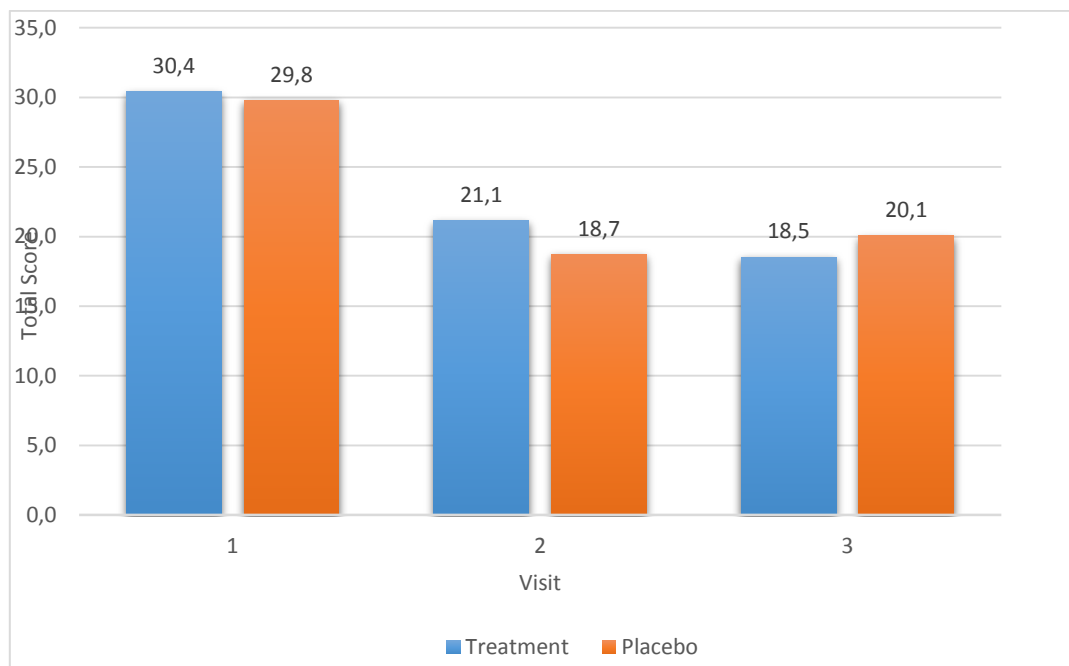
The placebo group response demonstrated a slight improvement which could have been because they were talking about their symptoms so were mentally they were emotionally accepting the symptoms and dealing with the outcome.

Figure 4.4 and Figure 4.5 show bar charts of the results presented in Table 4.3.





**Figure 4.4: VAS results**



**Figure 4.5: KPD results**

From the figures one can see that there is a decreasing trend in the scores for both groups on both scales.

The treatment group's lowest VAS score was on visit 2 and lowest KPD score was on visit 3.

Table 4.4 shows the results of the differences in the scores between the groups.

A normality test revealed that most of the distributions were not normal. Hence, non-parametric tests were used to compare the group scores. The results are shown below for the Mann Whitney and Wilcoxon W tests.

**Table 4.4: Table of Statistics tests using Mann-Whitney U and Wilcoxon W tests**

	V1	V2	V3	K1	K2	K3
Mann-Whitney U	87.000	78.500	101.500	104.000	90.500	99.500
Wilcoxon W	207.000	198.500	221.500	224.000	210.500	219.500
Z	-1.060	-1.414	-.457	-.353	-.916	-.541
Asymp. Sig. (2-tailed)	.289	.157	.648	.724	.359	.589
Exact Sig. [2*(1-tailed Sig.)]	.305 <sup>b</sup>	.161 <sup>b</sup>	.653 <sup>b</sup>	.744 <sup>b</sup>	.367 <sup>b</sup>	.595 <sup>b</sup>

a. Grouping Variable: Group

b. Not corrected for ties.

The traditional approach to reporting a result requires a statement of statistical significance. A *p*-value is generated from a test statistic. A significant result is indicated with "*p* < 0.05". It is noted that the differences observed per visit per scale were not significantly different. That is, the treatment and placebo groups showed similar results. A more detailed analysis per visit between the groups yielded the results in Table 4.5.

**Table 4.5: Detailed analysis per visit between the groups**

	Mann-Whitney U	Wilcoxon W	Z	Asymp. Sig. (2-tailed)	Exact Sig. [2*(1-tailed Sig.)]
V1.1	96.000	216.000	-0.694	0.488	.512
V1.2	93.000	213.000	-0.820	0.412	.436
V1.3	82.500	202.500	-1.257	0.209	.217
V1.4	97.000	217.000	-0.653	0.514	.539
V1.5	105.500	225.500	-0.300	0.764	.775
V1.6	111.000	231.000	-0.063	0.950	.967
V2.1	77.000	197.000	-1.502	0.133	.148
V2.2	59.500	179.500	-2.242	0.025	.026
V2.3	96.500	216.500	-0.674	0.501	.512
V2.4	92.000	212.000	-0.864	0.388	.412
V2.5	86.000	206.000	-1.111	0.267	.285
V2.6	103.000	223.000	-0.397	0.691	.713

V3.1	90.000	210.000	-0.946	0.344	.367
V3.2	106.500	226.500	-0.253	0.800	.806
V3.3	102.000	222.000	-0.444	0.657	.683
V3.4	77.000	197.000	-1.499	0.134	.148
V3.5	112.000	232.000	-0.021	0.983	1.000
V3.6	87.500	207.500	-1.055	0.292	.305
K1.1	94.000	214.000	-0.820	0.412	.461
K1.2	102.000	222.000	-0.449	0.653	.683
K1.3	85.500	205.500	-1.157	0.247	.267
K1.4	93.500	213.500	-0.815	0.415	.436
K1.5	94.500	214.500	-0.788	0.431	.461
K1.6	112.500	232.500	0.000	1.000	1.000
K1.7	107.000	227.000	-0.233	0.816	.838
K1.8	110.500	230.500	-0.086	0.931	.935
K1.9	101.500	221.500	-0.468	0.639	.653
K1.10	96.000	216.000	-0.706	0.480	.512
K2.1	106.500	226.500	-0.263	0.793	.806
K2.2	92.500	212.500	-0.898	0.369	.412
K2.3	110.000	230.000	-0.114	0.909	.935
K2.4	95.500	215.500	-0.778	0.437	.486
K2.5	85.000	205.000	-1.186	0.236	.267
K2.6	112.000	232.000	-0.022	0.982	1.000
K2.7	81.000	201.000	-1.387	0.166	.202
K2.8	93.000	213.000	-0.879	0.380	.436
K2.9	99.000	219.000	-0.589	0.556	.595
K2.10	82.500	202.500	-1.447	0.148	.217
K3.1	112.000	232.000	-0.022	0.983	1.000
K3.2	78.500	198.500	-1.531	0.126	.161
K3.3	87.500	207.500	-1.205	0.228	.305
K3.4	104.000	224.000	-0.413	0.679	.744
K3.5	108.000	228.000	-0.196	0.844	.870
K3.6	96.000	216.000	-0.732	0.464	.512
K3.7	91.500	211.500	-0.910	0.363	.389
K3.8	110.000	230.000	-0.115	0.908	.935
K3.9	90.500	210.500	-0.976	0.329	.367
K3.10	99.000	219.000	-0.720	0.471	.595

Only one reading shows a significant difference ( $p < .026$ ).

#### 4.4.1 Comparisons of the two scales VAS and KPD

As the scales do not have the same measurement levels, total scores were obtained for the various items that constituted the scales. Various correlation techniques (Pearson, Spearman and Kendall's tau-b) were used to determine the relationship between the scores. Bivariate correlation was performed on the data.

Table 4.6 shows that the results varied but showed significant relationships between the same pairs in all of the correlation methods.

**Table 4.6: Comparison of VAS and KPD**

		V1	V2	V3	K1	K2	K3
V1	Pearson Correlation	1					
	Sig. (2-tailed)						
	N	30					
V2	Pearson Correlation	-0.278	1				
	Sig. (2-tailed)	0.136					
	N	30	30				
V3	Pearson Correlation	0.078	0.267	1			
	Sig. (2-tailed)	0.682	0.154				
	N	30	30	30			
K1	Pearson Correlation	.658**	-0.088	0.105	1		
	Sig. (2-tailed)	0.000	0.645	0.581			
	N	30	30	30	30		
K2	Pearson Correlation	0.211	.412*	.558**	0.354	1	
	Sig. (2-tailed)	0.262	0.024	0.001	0.055		
	N	30	30	30	30	30	
K3	Pearson Correlation	-0.100	.398*	.526**	-0.037	.495**	1
	Sig. (2-tailed)	0.598	0.029	0.003	0.845	0.005	
	N	30	30	30	30	30	30

\*\* . Correlation is significant at the 0.01 level (2-tailed).

\* . Correlation is significant at the 0.05 level (2-tailed).

The results indicate the following patterns. Positive values indicate a directly proportional relationship between the variables and a negative value indicates an inverse relationship. All significant relationships are indicated by a \* or \*\*. For example, the correlation value between “V1” and “K1” is 0.3658. This is a directly related proportionality. The more V1 increases, so does K1, and vice versa. Since the scale directions are the same, the same effect is being detected.

Figures 4.6 to 4.8 show more detailed KPD series where there is a decrease in pain/discomfort. However, overall differences are the same: differences are not significant.

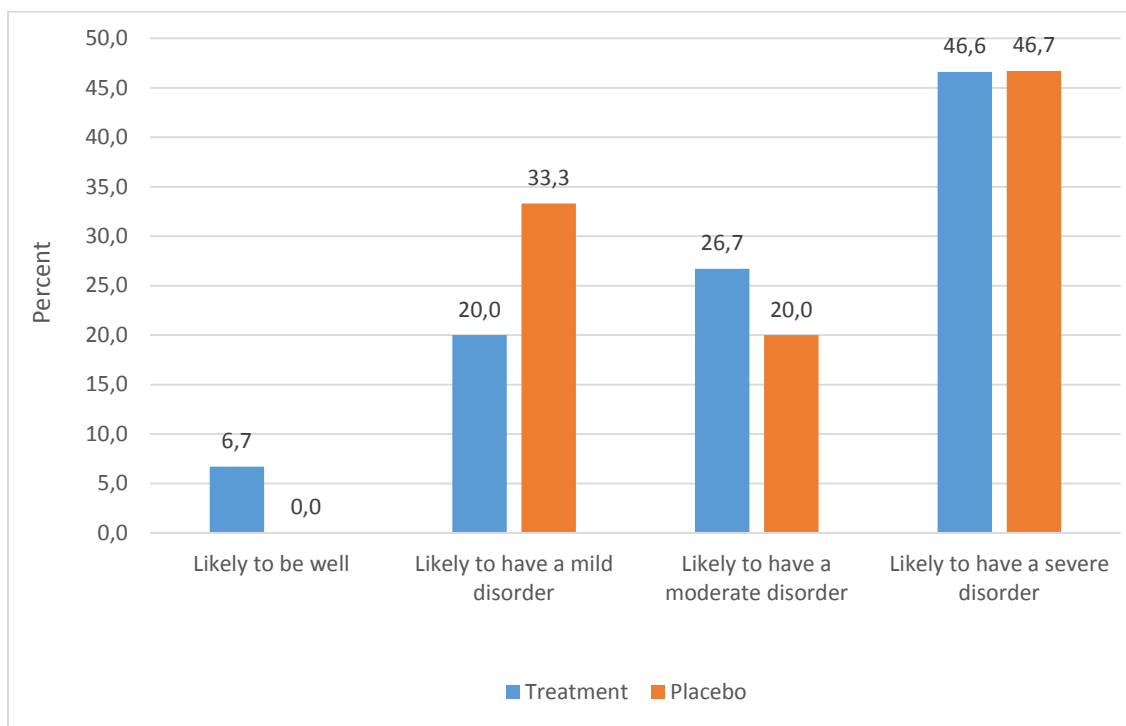
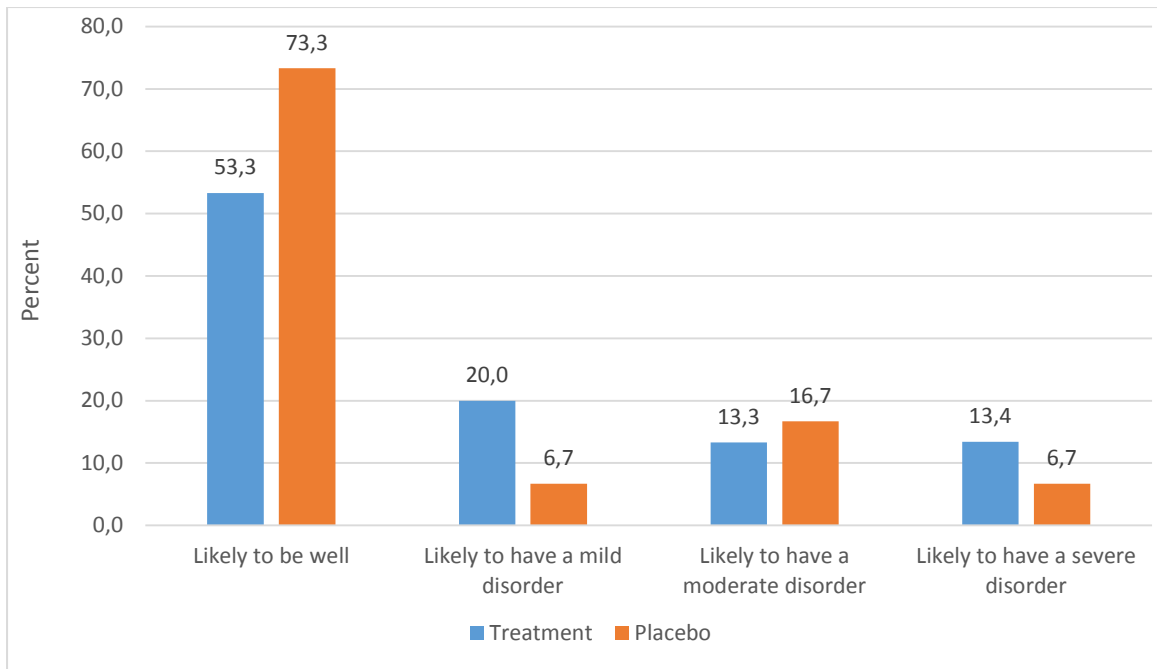
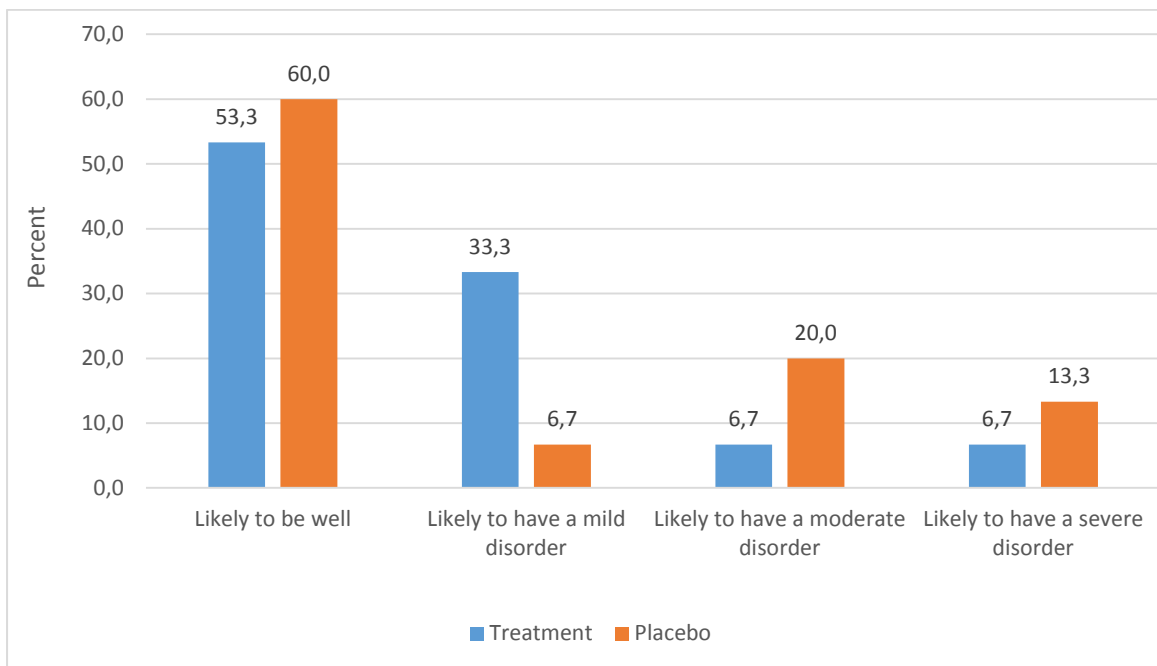


Figure 4.6: KPD V1



**Figure 4.7: KPD V2**



**Figure 4.8: KPD V3**

Looking at both the treatment group and the placebo group results there is not much difference when comparing the outcome results. The treatment group shows a slight improvement in the symptoms of pain and discomfort.

## **CHAPTER 5: DISCUSSION**

### **5.1 INTRODUCTION**

The aim of the study was to determine the efficacy of a homoeopathic complex treatment containing (*Sepia officinalis* 30CH, *Pulsatilla pratensis* 30CH, *Passiflora incarnata* 30CH, *Kalium phosphoricum* 30CH and *Natrium muriaticum* 30CH) in controlling PMDD. The results of the study showed that there was no statistical significance between the two groups on both measurement tools. The traditional approach to reporting a result requires a statement of statistical significance. A p-value is generated from a test statistic. A significant result is indicated with " $p < 0.05$ ". It is noted that the differences observed per visit per scale were not statistically significant different. That is, the treatment and placebo groups showed similar results.

### **5.2 DEMOGRAPHIC INTERPRETATION**

The pie charts in Figures 4.1 to 4.3 shows that the average age range during the study was between the ages 18 to 30 years, which could be because most of the participants that participated in the study were students.

### **5.3 DISCUSSION OF THE RESULTS**

The results obtained from the study related to the signs and symptoms of PMDD which underly the diagnosis of PMDD. The VAS scale measured the following signs and symptoms:.

1. Before your menses start how do you feel?
2. Rate your depression and irritability
3. Rate your anxiety
4. Rate your energy levels
5. How is your sleeping pattern?
6. How is your normal lifestyle like a week before your menses?

The treatment group VAS results shown in Figure 4.4 indicate that the lowest score was on the second visit. However, the  $p$ -value generated from this result was not less than 0.05 which shows that per visit there was no significant difference between the treatment and placebo groups.

The Kessler scale measured the following signs and symptoms of the participants.

In the past 4 weeks how often did the participant feel:

1. Feel tired for no good reason?
2. Feel nervous?
3. Feel nervous nothing could calm you down?
4. Feel hopeless?
5. Feel restless and fidgety?
6. Feel restless and could not sit still?
7. Feel depressed?
8. Feel everything was an effort?
9. Feel sad nothing could cheer up?
10. Feel worthless?

Figure 4.8 shows results from V3 of the KPD scale where it is evident that there was a decrease in the severity of pain and discomfort for both groups. These are some of the symptoms which patients with PMDD present with.

The KPD results revealed the more emotional aspect of the PMDD symptoms, but overall the results were not statistically significant. The treatment group only showed lower scores on their third visit but this was not statistically significant.

Comparing the age groups that participated in the study the more matured group which is the 31-35 years not so many participants took part and psychologically being more mature it's the group that was expected to have experienced more of the signs and symptoms of PMDD. The values of the results would have showed more significant results. Figure 4.4 and 4.5 illustrates the VAS scale results of both groups and from the results no significant results was obtained from both groups because not much difference was gathered from the participants.



Participants fully understood the scales and rated their symptoms according to how they felt or experienced them. Perhaps the reason why the results were not statistically significant was that participants only rated the symptoms once a month and not on a daily base scale throughout the study duration. The outcome might have improved if participants had diarised their symptoms on a daily base for the full duration of the study, However, diarising the symptoms on a daily basis could have been too onerous, and days might have been missed, which would have affected the results. Therefore, diarising the symptoms on a daily base may not have been ideal.

#### **5.4 OTHER FACTORS WHICH AFFECTED THE STUDY**

The researcher proposes that the study duration was not long enough to produce better results. Perhaps there was not enough time allowed for the medication to produce an effect. With a longer duration the result may have been different to the results obtained. Most interventions for PMDD are implemented for longer periods than 3 months and they yield better results.

Another factor to be considered is the sample size which was not a true reflection of the society at large and did not fully represent the people affected by PMDD. The costs of running a full clinical trial within the institution are excessive which was why for this project the sample size was restricted to 30 participants. However, a small sample size cannot yield results that can be generalised to the wider population.

The remedy combination used for the study were expected to significantly improve the symptoms assessed by the VAS scale. homoeopathic remedies are prescribed to patients with similar symptoms to as the remedy itself. Looking at the remedy selection:

- *Sepia officinalis*: The remedy symptoms that stand out is sadness which leads to irritability.
- *Pulsatilla pratensis*: The remedy has a symptom of being very irritable.
- *Passiflora incarnata*: This is an insomnia remedy that when given it is likely to produce normal sleep patterns when prescribed at the appropriate dosage.

- *Kalium phosphoricum*: This remedy presents tiredness as a main symptom. Individuals that would find this remedy suitable are those with marked depression, lethargy, physical exhaustion and are easily irritated.
- *Natrum muriaticum*: This remedy is closely associated with the kind of depression where the patient wants to be left alone. Depression that follows after grief – the patient is hopeless, and cries alone.

The combination of remedies in the complex was good as they are the major remedies that appear high on the list on repertorisation of PMDD symptoms. The researcher would not consider changing the selection, but the dosage and frequency could be reviewed. The remedies in a complex do not seem to have the same effect as singular remedies. The remedies selected do not have an anti-doting effect on one another, but possibly they could have competed for mechanisms of action within the individual. Since a complex does not take into account the individuality factor, the complex used in this study could have worked well for some participants but not for all, so the results of the collective might not reflect the individual results. For this reason, the researcher recommends singular prescriptions for future studies.

The results showed no significant statistical difference between the two groups. Therefore, the homoeopathic complex *Sepia officinalis* 30CH, *Pulsatilla pratensis* 30CH, *Passiflora incarnata* 30CH, *Kalium phosphoricum* 30CH and *Natrum muriaticum* 30CH was no more effective than the placebo in the management of PMDD, as neither intervention proved to be more superior than the other.

## 5.5 PLACEBO EFFECT

An important component of this discussion is the possible effect of a placebo. Placebo is a substance with no active biological properties. In a controlled clinical trial, it is used as an inactive agent that plays the role of a standard of comparison for the substance or method to be tested and is indistinguishable from it (Swayne 2000: 162). However, in the current study, one can question the “inactive” nature of the placebo. For the purpose of this trial, placebo was used as a control, to determine the efficacy of the homoeopathic complex. The fact that the participants in the placebo group were

listened to with sympathy, and received something i.e. an oral dose of an “inactive” substance indistinguishable from an active homoeopathic complex could have been enough to help them improve their symptoms.

However, this then raises an important question: will every placebo group improve to a certain degree and if so, is this an effective means by which to compare a new intervention? How much of a placebo improvement is allowed to approve or disapprove the effectiveness of an intervention? According to Benson and Friedman (1996: 194-195), the placebo is the aspect of treatment not attributable to specific pharmacologic or physiologic properties. They have proposed that the determinants of the placebo effect are a positive belief and expectation on the part of the patient, a positive belief and a positive belief of expectation on the part of the physician, and a good relationship existing between both the patient and physician. It is possible that all three determinants were in place during this study. Both groups in this study received an oral dose of a “medicine”, thus the positive improvement within all the groups could be attributable to this placebo effect.

## **5.6. OTHER RELATED STUDIES**

There are not enough studies with similar treatment protocol, measuring tools and duration as this one for it to be compared with, hence it is recommended that more clinical trials be conducted in the field to expand the data available and the scope of treatment for this condition.

The results of the study concurs with the study of Atmaca et al 2003 which showed no statistical evidence in favour of *Vitex Agnus catus* in the treatment of PMMD their results however showed that the extract was more effective on physical symptoms. Most researches focus more on the use of *Vitex agnus custus* in the management of PMS and not enough researches have been done on the use of homoeopathic tinctures in the management of PMDD.

A double blind( $p=0.04$ ) study on healthy volunteers done by Carny and Schmid (1999) provided no statistical evidence in favour of tolerability and efficacy of *Valeriana officinalis* and *Melissa officinalis* compared to the placebo group. The study of Kennedy

et al 2006 showed different results that the combination of Melissa and Valeriana ameliorated the negative effect of Dened Intensity Stressor Simulation (DISS) battery on ratings of anxiety, they concluded that the combination of Valeriana officinalis and Mellisa officinalis have anxiolytic effect and further investigations rendered.

# CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

## 6.1 INTRODUCTION

The aim of this study was to determine the efficacy of the homoeopathic complex *Sepia officinalis* 30CH, *Pulsatilla pratensis* 30CH, *Passiflora incarnata* 30CH, *Kalium phosphoricum* 30CH and *Natrium muriaticum* 30CH in the management of PMDD.

This chapter looks at the overall outcome of the study and discusses the possible limitations that affected the outcome of the results, and makes recommendations for future similar studies.

## 6.2 CONCLUSION

An inherent problem in clinical studies involving homoeopathic interventions is the paradigm in which the results are analysed. Today everything must be measured. This has resulted in quantification of everything with the consequence that those phenomena and experiences which are qualitative are denigrated and even regarded as having no reality. All our inner life, our souls, emotions are qualitative. To exclude these is to exclude our very human reality and we are today in great danger of forgetting that we are the measurers and not only measurable objects (Twentyman, 1989: 35). Furthermore, placebo responses are augmented by the very nature of this study, the reason being that the placebo targets the patient's superficial perception and expectation. When a patient seeks professional help, he or she expects to get better and this expectation is enhanced when he or she receives medication (Hanekom, 2002: 4-9). In this study, therefore, one can say that the placebo effect inherently targeted one of the variables of interest in this study, as it works at a perceptual level.

This study concludes that no significant results were obtained with the number of participants that took part in the study and thus further studies are recommended to advance knowledge of treatment protocols for this condition PMDD.

### **6.3 LIMITATIONS OF THE STUDY**

The following are the limitations that may have possibly played a role on the outcome of the study:

- a) The time allocated to see participants at the clinic only favoured students and the people who are unemployed, limiting the people who are at work during the day from participating.
- b) The study only focused on Durban, KwaZulu-Natal, participants which excluded other provinces.
- c) The small number of participants (30).

### **6.4 RECOMMENDATIONS**

- a) To perform the study for a longer duration than 3 months, possibly a maximum of two years.
- b) To do the study in all the provinces so as to gain more comparable results and increase participant diversity.
- c) The sample size used in further investigations should be larger in order to obtain greater statistical accuracy.
- d) To perform the study with more flexible consultation hours which would be favourable to everyone who is interested in participating.
- e) Use different potencies of the ingredients.
- f) Conduct simillimum studies, which may be more appropriate.
- g) PMDD is a multifaceted problem therefore it is recommended that homoeopathic treatment be evaluated together with lifestyle adjustments such as diet and exercise.
- h) Compare samples from different socio-economic or from different cultural to determine if these variables have any influence on outcome.

## REFERENCES

A.D.A.M. Medical encyclopaedia. 2016. Premenstrual dysphoric disorder. Available: <https://medlineplus.gov/ency/article/007193.htm> (Accessed 26 June 2016).

American Academy of Family Physicians. Dysthymic Disorder. 2011 .available <https://familydoctor.org/condition/dysthymic-disorder/> (Accessed 21 March 2017).

American College of Obstetricians and Gynecologists (ACOG) 2000. Premenstrual Syndrome, vol 15. ACOG, Washington, D.C.

American Psychiatric Association.1994. Diagnostic and Statistical Manual of Mental Disorders. Fourth Edition. IV DSM-IV. Paperback. USA.

American Psychiatric Association.2013 Diagnostic and Statistical Manual of Mental Disorders. Fifth Edition. V DSM-IV. Paperback. USA.

Andrews G and Slade T. 2001. Interpreting scores on the Kessler Psychological Distress Scale (K10) *Australia and New Zealand Journal of Public Health*, 25(6): 494-497.

Ashpari Z. 2014. The calming effects of Passionflower. Available: <http://www.healthline.com/health/anxiety/calming-effects-of-passionflower#1> (Accessed 30 July 2015).

Benson, H and Friedman, R. 1996. Harnessing the power of the placebo effect and renaming it "remembered wellness". *Annual Review of Medicine*, 47: 193-199.

Berger et.al 1999 *Journal of Neurophysiology* 17-B Estradiol enhances NMDA Receptors-mediated EPSPs and long term potentiation

Bhatia S and Bhatia S. 2002. Diagnosis and treatment of premenstrual dysphoric disorder. *American Family Physician*, 66(7): 1239-1249.

Bodian, C., Freedman, G., Hossain, S., Eisenkraft, J. and Beilin, Y. 2001. The visual analog scale for pain: clinical significance in postoperative patients. *Anesthesiology*, 95(6): 1356-1361.

Boericke W. 1999. *Homœopathic materia medica*. Available: <http://www.homeoint.org/books/boericmm/p/puls.htm> (Accessed 26 June 2014).

Bordet, M. F., Marijnen, P., Masson, J., and Trichard, M. 2008. Treating hot flushes in menopausal women with homoeopathic treatment – results of an observational study. *Homeopathy*, 97(1): 10-15.

Brown 1994, 1455-1458 Estrogen receptor-associated proteins possible mediators of hormone-induced transcription.

Coco, A. S. 1999. Primary dysmenorrhea. *American Family Physician*, 60(2): 489-496.

Crichton, N. 2001. Information point: visual analogue scale (VAS). *Journal of Clinical Nursing*, 10(5): 697-706.

Danno, K., Colas, A., Terzan, L., and Bordet, M. 2013. Homoeopathic treatment of premenstrual syndrome: a case series. *Homeopathy* (102) 59-65.

De Schepper, L. 2001. *Hahnemann revisited*. Santa Fe: Full of Life Publications.

Diagnostic and Statistical Manual of Mental Disorders. 2000. 4<sup>th</sup> ed. Arlington: American Psychiatric Association.

Diagnostic and Statistical Manual of Mental Disorders. 2013. 5<sup>th</sup> ed. Arlington: American Psychiatric Association.

Dreyer, A. C., Dreyer, M. S., Hattingh, E. and Thandar, Y. 2013. *Antidepressants. Pharmacology for nurses and other health workers*. 3<sup>rd</sup> ed. Cape Town: Pearson.



Elliot Premenstrual Dysphoric Disorder N.C Med J. 2002

Friedman, H. 1998. *Encyclopedia of mental health-Vol. 1*. San Diego, CA: Academic Press.

Gallagher, E. J., Bijur, P. E., Latimer, C. and Silver, W. 2002. Reliability and validity of a visual analog scale for acute abdominal pain in the ED. *The American Journal of Emergency Medicine*, 20(4): 287-290.

Giudice, L. C., Tazuke, S. I. and Swiersz, L. 1998. Status of current research on endometriosis. *Journal of Reproductive Medicine*, 43: 252-262.

Google Images. 2016. Available: <http://www.google.com/images?q=menstruation> images.com (Accessed 10 August 2016).

Grady-Weliky M.D Premenstrual Dysphoric Disorder 2003, 348: 433-438

Hanekom, F. 2002. Communication. Vol. 9: 4.

Haven, C. and Sullivan, N. 2002. *Manual of outpatient gynaecology*. 4<sup>th</sup> ed. Philadelphia, PA: Lippincott Williams and Wilkins.

Hylan TR, Sundell K, Judge R. 1999. The impact of premenstrual symptomatology on functioning and treatment-seeking behaviour: experience from the United States, United Kingdom, and France. *J Women's Health Gend Based Med*. 1999 Oct;8(8):1043-52.

Kent, K. 2005. The effectiveness of an oral homoeopathic preparation of selenium sulphide 12X in the management of dandruff (seborrheic dermatitis of the scalp). M.Tech Durban University of Technology.

Kent, J. T. 2009. *Lectures on homeopathic philosophy*. Seaside, OR: Watchmaker Publishing.

Katz T. 1995. The management of pregnancy and labour with homoeopathy. *Complementary Therapies in Nursing and Midwifery*, 1(6): 159-164.

Kessler, C., Andrews, G., Colpe, J., Hiripi, E., Mroczek, D., Normand, S., Walters, E. and Zaslavsky, A. 2002. Short screening scales to monitor population prevalence's and trends in non-specific psychological distress. *Psychological Medicine*, 32(6): 959-976.

Kessler, R., Barker, P., Barker, P. R., Colpe, L. J., Epstein, J. F., Gfroerer, J. C., Hiripi, E. et al. 2003. Screening for serious mental illness in the general population. *Archives of General Psychiatry*, 60(2): 18418-9.

KN Muse 1990;427-440 Obstetrics and gynaecology clinics of North America.

Laister C. 2008. The efficacy of homoeopathic simillimum in the treatment of premenstrual syndrome (PMS). M.Tech Durban University of Technology.

Llewellyn-Jones, R. H., Baikie, K. A., Smithers, H., Cohen, J., Snowdon, J. and

Loch, E., Selle, H. and Boblitz, N. 2000. Treatment of premenstrual syndrome with a phytopharmaceutical formulation containing *Vitex agnus castus*. *Journal of Women's Health and Gender Based Medicine*, 9(3): 315-320.

Lockie, A. and Geddes, N. 2005. *The complete guide to homeopathy*. London: Dorling Kindersley.

Lustyk, M., Gerrish, W., Shaver, S. and Keys, S. 2009. Cognitive-behavioural therapy for premenstrual syndrome and premenstrual dysphoric disorder: a systematic review. *Women's Mental Health*, 12(2): 85-96.

Menkes, D. B, Taghavi, E., Mason, P. A., Spears, G. F. S. and Howard, R. C. 1992. Fluoxetine treatment of severe premenstrual syndrome. *British Medical Journal*. 305(6849): 346-347.

Merck manual (2011) The diagnosis and Therapy 19<sup>th</sup> edition

Mortal 1993 Clinical applications of Mifepristone and other antiprogestins

Murphy, R. 2003. Homeopathic clinical repertory: a modern alphabetical and practical repertory. 3<sup>rd</sup> ed. Blacksburg, VA: H.A.N.A. Press.

Murray and Lopez (1996: 1-23 Estrogen effect in Psychiatric Disorders

Muse, K. 1992. Hormonal manipulation in the treatment of premenstrual syndrome. *Clinical Obstetrics and Gynecology*, 35(3) :658-66.

Niederhofer 2009, 39 1145-1154 Pharmacotherapy and Pathophysiologi approach

Nordqvist, C. (2018). All about antidepressants.

<https://www.medicalnewstoday.com/articles/248320.php>

Parsey and Pong. 2000; 105-111 An open- label multicentre study to evaluate Yasmin a low dose combination oral contraceptive containing drospirenone a new progestogen

Price, D. D., Staud, R. and Robinson, M. 2012. How should we use the visual analogue scale in rehabilitation outcomes? Visual analogue scale as ratio scales: an alternative to the view of Kersten et al. *Journal of Rehabilitation Medicine*, 44(9): 800-801.

O'Reilly, W. B (ed.). 1996. Organon of the medical art by Dr Hahnemann. 6<sup>th</sup> ed. Redmond, WA: Birdcage Books.

Oxford English Dictionary. 2003. Placebo. Oxford: Oxford University Press.

Ramoupi K. 2012. The efficacy of *Thiosinaminum* 1X cream on striae. M.Tech University of Johannesburg.

Ravindren 2007 Genetic resources chromosomes engineering and crop improvement  
Medical plants

Sayegh et.al vol 35 1994 Cumulated index Medicus

Segebladh et al. (2009) pages 139 Evaluation of different add-back estradiol and progesterone treatments to gonadotropin-releasing hormone agonist treatment in patients with premenstrual dysphoric disorder

Steiner, M., Streiner, D., Steinberg, S., Stewart, D., Carter, D., Berger, C., Reid, R. and Grover, D. 1999. The measurement of premenstrual mood symptoms. *Journal of Affective Disorders*, 53(3): 269-273.

Stevinson, C. and Ernst, E. 2001. Complementary/alternative therapies for premenstrual syndrome: a systematic review of randomised controlled trials. *American Journal of Obstetrics and Gynecology*, 185(1): 227-235.

Stöppler M. 2013. Premenstrual dysphoric disorder (PMDD). Available: [http://www.medicinenet.com/premenstrual\\_dysphoric\\_disorder\\_pmdd/article.htm](http://www.medicinenet.com/premenstrual_dysphoric_disorder_pmdd/article.htm) (Accessed 26 June 2014).

Storck S, 2014. *Premenstrual dysphoric disorder*. Available: <http://www.nytimes.com/health/guides/disease/premenstrual-dysphoric-disorder/overview.html> (Accessed 26 June 2014).

Swart P and Dreyer, G. 2007. Premenstrual syndromes – an approach to diagnosis and treatment. *South African Family Practice*, 49(3): 20-22.

Swayne, J. 2000. *International dictionary of homoeopathy*. Edinburgh: Churchill Livingstone.

Tennant, C. C. 1999. Multifaceted shared care intervention for late life depression in residential care: randomised controlled trial. *British Medical Journal*, 319(7211): 676-682.

Teleman S. 2005. The effectiveness of topical homoeopathic preparation of *Selenium sulphide* 8X shampoo in the management of dandruff (*Pityriasis capitis*). M.Tech Durban University of Technology.

Thielen, J. M. 2015. What's the difference between premenstrual dysphoric disorder and premenstrual syndrome? How is PMDD treated? Available: <http://www.mayoclinic.org/diseases-conditions/premenstrual-syndrome/expert-answers/pmdd/faq-20058315> (Accessed 26 June 2014).

Twentyman, R. 1989. *The science and art of healing*. Edinburgh: Floris Books.

Vermeulen, F. 2001. *Concordant materia medica*. New Delhi: India Books and Periodicals Publishers.

Wiersma, W. and Jurs, S. G. 2009. *Research methods in education: an introduction*. 9<sup>th</sup> ed. Boston, MA: Pearson.

Wikander et.al 1998; 390-398 Citalopram in Premenstrual Dysphoric is intermittent treatment during Luteal phases more effective than continuous medication throughout the menstrual cycle.

Yakir, M., Kreitler, S., Brzezinski, A., Vithoulkas, G., Oberbaum, M. and Bentwich, Z. 2001. Effects of homoeopathic treatment in women with premenstrual syndrome: a pilot study. *British Homoeopathic Journal*, 90: 148-153.



# APPENDICES

## Appendix A: Information letter for participants (English)



### INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC) LETTER OF INFORMATION

Dear Participant

Thank you for agreeing to participate in this study.

**Title of the Research Study:** The efficacy of a Homoeopathic complex *Sepia*, *Pulsatilla pratensis*, *Passiflora incarnata*, *Kalium phosphoricum* and *Natrum muriaticum* in the management of Premenstrual Dysphoric Disorder (PMDD).

**Principal Investigator/s/researcher:** Ms Phumza Totongwana, B.Tech. Homoeopathy

**Co-Investigator/s/supervisor/s:** Dr. J. C. Ngobese-Ngubane, M. Tech. Hom. (Supervisor)

Dr. I. Couchman, M. Tech. Hom. (Co-supervisor)

**Brief Introduction and Purpose of the Study** The purpose of the proposed study is to determine the efficacy of a Homoeopathic complex treatment containing (*Sepia*, *Pulsatilla pratensis*, *Passiflora incarnata*, *Kalium phosphoricum* and *Natrum muriaticum*) in the management of Premenstrual Dysphoric Disorder (PMDD). PMDD as described by (DSM V-2013) is characterized by decrease daily functions emotionally and cognitive behavioural level. Decreased interest in usual activities (eg, work, school, friends, and hobbies). Subjective sense of difficulty in concentrating. Lethargy, easy fatigability, or marked lack of energy. Marked change in appetite, overeating, or specific food cravings. Hypersomnia or insomnia. A subjective sense of being overwhelmed or out of control.

**Outline of the Procedures:** The consultations where data relating to PMDD will be collected will take place at the Durban University of Technology (DUT), Homoeopathic Day Clinic (HDC). The total duration of the study is 3 months (12 weeks) with only 3 consultations AFTER EACH MENSTRUAL CYCLE. The Initial consultation will be about an hour long and thereafter the follow up consultations will be about 30 minutes long. You will be requested to complete the consent form before you may participate in this study. On consenting to participate you will be requested to provide a urine sample to make sure you are not pregnant because pregnant women may not be included in this study. You will then be required to complete the scales that will be explained to you. The completion of the scales may take 10 minutes. These scales will be completed before each consultation.

**Non-participation:** You are not forced to participate in this study. Participation in this study is voluntarily. If you don't participate in this study it will not affect the service offered to you by the HDC.

**Risks or Discomforts to the Participant:** There are no known risks associated with Homoeopathic consultation.

**Benefits:** The information given by you will help to draw conclusions about the efficacy of a Homoeopathic complex *Sepia*, *Pulsatilla pratensis*, *Passiflora incarnata*, *Kalium phosphoricum* and *Natrum muriaticum* in the management of Premenstrual Dysphoric Disorder (PMDD). You may also experience the ease of PMDD symptoms.

#### **What is expected of the participant?**

You will be given a 50ml oral drops. You will be taking 10 oral drops twice daily for the entire duration of the study. You are advised not to USE any other treatment for PMDD during the study period as this could affect the validity of the results. Full instructions on the administration of the medication will be given to you. There is a 50% chance that you will be in a treatment group that will get the active oral or in a control group that will get inactive oral drops. If you fall in the control group you will receive free homoeopathic treatment at the end of the study.

**Reason/s why the Participant May Be Withdrawn from the Study:** You are free to withdraw from the study at any time without any form of penalty.

**Remuneration:** There is no remuneration for participating in this study.



**Costs of the Study:** You will not be expected to cover any costs towards the study.

**Confidentiality:** Please do not write your personal information like name, contact details on the scales. All data collected will be pooled to ensure anonymity. Pooled data will be communicated scientifically. Data will be stored in a locked cupboard for 5 years

**Research-related Injury:** There are no injuries that you may be exposed to during the course of the study.

**Persons to Contact in the Event of Any Problems or Queries:**

Ms Phumza Totongwana (Student) Telephone no: 073 865 9873

Dr. J.C. Ngobese-Ngubane (Supervisor) Telephone no: 031 373 2484

Dr. I. Couchman (Co-supervisor) Telephone no: 031 373 2482

**The Institutional Research Ethics administrator:** - 031-373 2900. Complaints can be reported to the DVC: TIP F. Otieno on 031-3732382 or [dvctip@dut.ac.za](mailto:dvctip@dut.ac.za).

## Appendix B: Consent form for participants (English)



### INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC)

#### CONSENT

#### Statement of Agreement to Participate in the Research Study:

- I hereby confirm that I have been informed by the researcher, \_\_\_\_\_ (name of researcher), about the nature, conduct, benefits and risks of this study - Research Ethics Clearance Number: \_\_\_\_\_,
- I have also received, read and understood the above written information (Participant Letter of Information) regarding the study.
- I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.
- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the researcher.
- I may, at any stage, without prejudice, withdraw my consent and participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.
- I understand that significant new findings developed during the course of this research which may relate to my participation will be made available to me.

\_\_\_\_\_  
**Full Name of Participant**                      **Date**                      **Time**                      **Signature / Right**

**Thumbprint**

I, \_\_\_\_\_ (name of researcher) herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

\_\_\_\_\_  
**Full Name of Researcher**                      **Date**                      **Signature**

\_\_\_\_\_  
**Full Name of Witness (If applicable)**   **Date**                      **Signature**

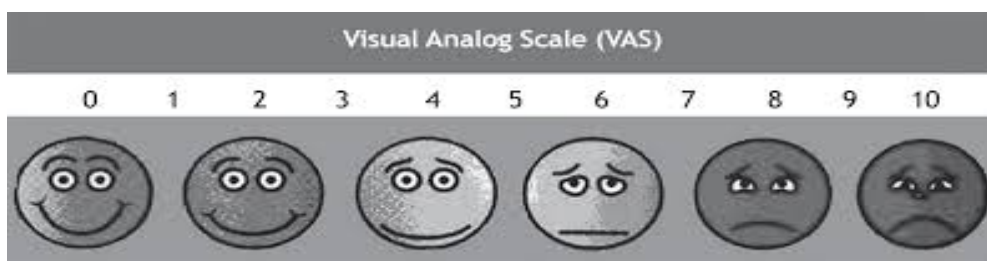
\_\_\_\_\_  
**Full Name of Legal Guardian (If applicable)** **Date**                      **Signature**

## Appendix C: Visual Analog Scale Form (VAS)



### Visual Analog Scale Form (VAS)

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From the list of symptoms and signs below rate how each make you feel choosing from the facial expressions provided above: **0 being very better and 10 being very worst**

1. Before your menses start how do you feel rate it?
2. Rate your depression and irritability?
3. Rate your anxiety
4. Rate your energy levels
5. How is your sleeping pattern?
6. How is your normal lifestyle like a week before your menses?

A Visual Analogue Scale (VAS) (Appendix C) is a measurement instrument that tries to measure a characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured. For example, the amount of pain that a patient feels ranges across a continuum from none to an extreme amount of pain. From the patient's perspective, this spectrum appears continuous i.e. their pain does not take discrete jumps, as a categorization of none, mild, moderate and severe would suggest. It was to capture this idea of an underlying continuum that the VAS was devised.

(Adapted from the DSM-IV 1995, Google images)

## Appendix D: Kessler Psychological Distress Scale (K10)



### Kessler Psychological Distress Scale (K10)

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Source: Kessler RC, Barker PR, Colpe LJ, Epstein JF, Gfroerer JC, Hiripi E, et al. Screening for serious mental illness in the general population. *Arch Gen Psychiatry*. 2003 Feb;60(2):184-9.

The Kessler Psychological Distress Scale (K10) <sup>111</sup> is a simple measure of psychological distress. The K10 scale involves 10 questions about emotional states each with a five-level response scale. The measure can be used as a brief screen to identify levels of distress. The tool can be given to patients to complete, or alternatively the questions can be read to the patient by the practitioner.

In the context of injury management, the measure can be provided to the patient where recovery is not proceeding as anticipated (for instance, between weeks four and six), and may highlight the need for more regular review, or referral to a specialist health provider such as a psychologist.

Questions three and six do not need to be asked if the response to the preceding question was 'none of the time'. In such cases questions three and six should receive an automatic score of one.

## Scoring instructions

Each item is scored from one 'none of the time' to five 'all of the time'. Scores of the 10 items are then summed, yielding a minimum score of 10 and a maximum score of 50. Low scores indicate low levels of psychological distress and high scores indicate high levels of psychological distress.

## Interpretation of scores

The 2001 Victorian Population Health Survey <sup>121</sup> adopted a set of cut-off scores that may be used as a guide for screening for psychological distress. These are outlined below:

K10 Score: Likelihood of having a mental disorder (psychological distress)

- 10-19 Likely to be well
- 20 - 24 Likely to have a mild disorder
- 25- 29 Likely to have a moderate disorder
- 30 - 50 Likely to have a severe disorder

## Kessler Psychological Distress Scale (K10)

Please tick the answer that is correct for you:	All of the time (score 5)	Most of the time (score 4)	Some of the time (score 3)	A little of the time (score 2)	None of the time (score 1)
1. In the past 4 weeks, about how often did you feel tired out for no good reason?					
2. In the past 4 weeks, about how often did you feel nervous?					
3. In the past 4 weeks, about how often did you feel so nervous that nothing could calm you down?					
4. In the past 4 weeks, about how often did you feel hopeless?					
5. In the past 4 weeks, about how often did you feel restless or fidgety?					
6. In the past 4 weeks, about how often did you feel so restless you could not sit still?					
7. In the past 4 weeks, about how often did you feel depressed?					
8. In the past 4 weeks, about how often did you feel that everything was an effort?					
9. In the past 4 weeks, about how often did you feel so sad that nothing could cheer you up?					
10. In the past 4 weeks, about how often did you feel worthless?					

## References

1. Kessler RC, Barker PR, Colpe LJ, Epstein JF, Gfroerer JC, Hiripi E, et al. Screening for serious mental illness in the general population. *Arch Gen Psychiatry*. 2003 Feb; 60(2):184-9.
2. Victorian Population Health Survey. Melbourne: Department of Human Services, Victoria; 2001.

## Appendix E: Inclusion criteria as per DSM V (2013)



### THE INCLUSION CRITERIA FOR PMDD AS STATED BY THE DSM V (2013)

Participants must meet the inclusion criteria for PMDD as stated by DSM V (2013).

Diagnostic Criteria	YES/NO
A. In most menstrual cycles during the past year, five (or more) of the following symptoms occurred during the final week before the onset of menses, started to improve within a few days after the onset of menses, and were minimal or absent in the week post menses, with at least one of the symptoms being either (1), (2), (3), or (4):	
(1) marked affective liability (e.g., mood swings; feeling suddenly sad or tearful or increased sensitivity to rejection) (2) marked irritability or anger or increased interpersonal conflicts (3) markedly depressed mood, feelings of hopelessness, or self-deprecating thoughts (4) marked anxiety, tension, feelings of being "keyed up" or "on edge" (5) decreased interest in usual activities (e.g., work, school, friends, hobbies) (6) subjective sense of difficulty in concentration (7) lethargy, easy fatigability, or marked lack of energy (8) marked change in appetite, overeating, or specific food cravings (9) hypersomnia or insomnia (10) a subjective sense of being overwhelmed or out of control (11) other physical symptoms such as breast tenderness or swelling, joint or muscle pain, a sensation of "bloating," weight gain	
B. The symptoms are associated with clinically significant distress or interferences with work, school, usual social activities or relationships with others (e.g. avoidance of social activities, decreased productivity and efficiency at work, school or home).	
C. The disturbance is not merely an exacerbation of the symptoms of another disorder, such as Major Depressive Disorder, Panic Disorder, Dysthymic Disorder, or a Personality Disorder (although it may be superimposed on any of these disorders).	
D. The symptoms are not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication or other treatment) or a general medical condition (e.g., hyperthyroidism).	

Criteria	YES/NO
1) Participants must be females between the ages 20-35 years.	
2) Participants must be living around Durban –KwaZulu-Natal.	
3) Participants must be willing to follow study requirements.	
4) Participants who are not on any treatment for PMDD.	
5) Participants are not having a chronic medical or mental condition.	
6) Participants must maintain her normal lifestyle during the study.	
7) Participants who are not pregnant or intending to conceive for the duration of the study.	
8) Participants who have not had surgery in the past six weeks.	
9) Participants who are not on any recreational drugs.	

## Appendix F: Permission letters

### Appendix Fa: Permission Application Letter to use Homoeopathic Day Clinic (HDC), HOD: Homoeopathy Department



### Permission Application Letter to use Homoeopathic Day Clinic (HDC) HOD: Homoeopathy Department

P. O. Box 346  
6 Kirk Road  
Pinetown  
3600

Faculty of Health Sciences  
Department of Homoeopathy  
Head of Department  
P.O. BOX 1334  
Durban  
4000

Dear Dr Hall

#### **Permission Application Letter to use the Homoeopathic Day Clinic (HDC)**

Thank you for reading this letter. My name is Ms. Phumza Totongwana (20710958). I am currently registered for M. Tech. Homoeopathy and I am requesting to conduct my research study at the Homoeopathic Day Clinic (HDC). The efficacy of a Homoeopathic complex *Sepia*, *Pulsatilla pratensis*, *Passiflora incarnata*, *Kalium phosphoricum* and *Natrum muriaticum* in the management of Premenstrual Dysphoric Disorder (PMDD).

**Outline of the Procedures:** The consultations where data relating to PMDD will be collected will take place at the Durban University of Technology (DUT), Homoeopathic Day Clinic (HDC). The total duration of the study in 3 months (12 weeks) with only 3 consultations AFTER EACH MENSTRUAL CYCLE. The Initial consultation will be about an hour long and thereafter the follow up consultations will be about 30 minutes long. Participants will be requested to complete the consent form before you may participate in this study. On consenting to participate participants will be requested to complete the scales that will be explained to them. The completion of the scales may take 10 minutes. These scales will be completed before each consultation.

Yours sincerely

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Ms. Phumza Totongwana (20707749) – Researcher: 073 865 9873

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Dr. J. Ngobese-Ngubane (Supervisor) – 031 373 2484 ([jabulilen@dut.ac.za](mailto:jabulilen@dut.ac.za))

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Dr. I. Couchman - 031 373 2482 ([ingridc@dut.ac.za](mailto:ingridc@dut.ac.za))



**Appendix F (b): Permission Application Letter to use Homoeopathic Day Clinic (HDC), Homoeopathic Clinic Director & Coordinator**



**Permission Application Letter to use Homoeopathic Day Clinic (HDC)**

**Homoeopathic Clinic Director & Coordinator:**

P. O. Box 346  
6 Kirk Road  
Pinetown  
3600

Faculty of Health Sciences  
Clinic Director and Coordinator of Homoeopathic Day Clinic  
P.O. BOX 1334  
Durban  
4000

Dear Dr Nienaber & Dr Korporaal

**Permission Application Letter to use the Homoeopathic Day Clinic (HDC)**

Thank you for reading this letter. My name is Ms. Phumza Totongwana (20710958). I am currently registered for M. Tech. Homoeopathy and I am requesting to conduct my research study at the Homoeopathic Day Clinic (HDC). The efficacy of a Homoeopathic complex *Sepia*, *Pulsatilla pratensis*, *Passiflora incarnata*, *Kalium phosphoricum* and *Natrum muriaticum* in the management of Premenstrual Dysphoric Disorder (PMDD).

**Outline of the Procedures:** The consultations where data relating to PMDD will be collected will take place at the Durban University of Technology (DUT), Homoeopathic Day Clinic (HDC). The total duration of the study in 3 months (12 weeks) with only 3 consultations AFTER EACH MENSTRUAL CYCLE. The Initial consultation will be about an hour long and thereafter the follow up consultations will be about 30 minutes long. Participants will be requested to complete the consent form before you may participate in this study. On consenting to participate participants will be requested to complete the scales that will be explained to them. The completion of the scales may take 10 minutes. These scales will be completed before each consultation.

Yours sincerely.

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Ms. Phumza Totongwana (20707749) – Researcher: 073 865 9873

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Dr. J. Ngobese-Ngubane (Supervisor) – 031 373 2484 (jabulilen@dut.ac.za)

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Dr. I. Couchman - 031 373 2482 (ingridc@dut.ac.za)

**Appendix F (c): Permission Application Letter to use Homoeopathic Day Clinic (HDC), Director: Research and Postgraduate Support**



**Permission Application Letter to use Homoeopathic Day Clinic (HDC)  
Director: Research and Postgraduate Support**

P. O. Box 346  
6 Kirk Road  
Pinetown  
3600

Director: Research and Postgraduate Support  
Tromso Annex, 1st Floor  
Gate 1, Steve Biko Campus  
P.O. BOX 1334  
Durban  
4000

Dear Professor Moyo

**Permission Application Letter to use the DUT facility, students and staff**

Thank you for reading this letter. My name is Ms. Phumza Totongwana (20710958). I am currently registered for M. Tech. Homoeopathy and I am requesting to conduct my research study at the Homoeopathic Day Clinic (HDC). The efficacy of a Homoeopathic complex *Sepia*, *Pulsatilla pratensis*, *Passiflora incarnata*, *Kalium phosphoricum* and *Natrum muriaticum* in the management of Premenstrual Dysphoric Disorder (PMDD).

**Outline of the Procedures:** The consultations where data relating to PMDD will be collected will take place at the Durban University of Technology (DUT), Homoeopathic Day Clinic (HDC). The total duration of the study in 3 months (12 weeks) with only 3 consultations AFTER EACH MENSTRUAL CYCLE. The Initial consultation will be about an hour long and thereafter the follow up consultations will be about 30 minutes long. Participants will be requested to complete the consent form before you may participate in this study. On consenting to participate participants will be requested to complete the scales that will be explained to them. The completion of the scales may take 10 minutes. These scales will be completed before each consultation.

Clinic (HDC). The total duration of the study in 3 months (12 weeks) with only 3 consultations AFTER EACH MENSTRUAL CYCLE. The Initial consultation will be about an hour long and thereafter the follow up consultations will be about 30 minutes long. Participants will be requested to complete the consent form before you may

participate in this study. On consenting to participate participants will be requested to complete the scales that will be explained to them. The completion of the scales may take 10 minutes. These scales will be completed before each consultation.

Yours sincerely.

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Ms. Phumza Totongwana (20707749) – Researcher: 073 865 9873

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Dr. J. Ngobese-Ngubane (Supervisor) – 031 373 2484 (jabulilen@dut.ac.za)

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Dr. I. Couchman - 031 373 2482 (ingridc@dut.ac.za)

**Appendix F (d): Application Letter to use Notice Boards to paste advert for research**



**Application Letter to use Notice Boards to paste advert for research**

Faculty of Health Sciences  
Department of Homoeopathy  
P.O. BOX 1334  
Durban  
4000

To whom it may concern.

Dear Sir/ Madam

Permission Letter to use Notice Boards for pasting research advert

Ms. Phumza Totongwana (20710958). I am currently registered for M. Tech. Homoeopathy and I am requesting to conduct my research study at the Homoeopathic Day Clinic (HDC). The efficacy of a Homoeopathic complex *Sepia*, *Pulsatilla pratensis*, *Passiflora incarnata*, *Kalium phosphoricum* and *Natrum muriaticum* in the management of Premenstrual Dysphoric Disorder (PMDD).

Outline of the details of research advert: The advert outlines the symptoms of PMDD, location of the study, name of the researcher, contact details of the researcher and location of the study and that participation is free.

For further information regarding this study please contact the researcher or supervisors of the study.

Thanking you in advanced for your assistance in the above request.

Yours sincerely.

\_\_\_\_\_  
Ms. Phumza Totongwana (20707749) – Researcher: 073 865 9873

\_\_\_\_\_  
Dr. J. Ngobese-Ngubane (Supervisor) – 031 373 2484 (jabulilen@dut.ac.za)

\_\_\_\_\_  
Dr. I. Couchman - 031 373 2482 (ingridc@dut.ac.za)

## Appendix G: Statistical approach



### STATISTICAL APPROACH

*Descriptive statistics* describes the organising and summarising of quantitative data. Univariate and bivariate analysis is most appropriate for descriptive statistics. Univariate analysis is concerned with measures of central tendency and measures of dispersion. The most appropriate measure of central tendency for interval data is the mean and the most appropriate measure of dispersion for interval data is the standard deviation. Bivariate analysis concerns the measurement of two variables at a time. Descriptive statistics is useful as it summarises results for an experiment, thereby also allowing for more constructive research after more detailed analysis. Descriptive data analysis aims to describe the data the investigating the distribution of scores on each variable, and by determining whether the scores on different variables are related to each other. This can also be done using various types of tables and graphs.

### SAMPLING

Purposive, Stratified sampling

Involves dividing the group into subgroups or strata. Each stratum is homogeneous with respect to the characteristics being studied.

### MEASUREMENT

Nominal (or categorical) is a classification of responses (e.g. Gender).

Ordinal measurement is achieved by ranking (e.g. the use of a 1 to 5 rating scale from 'strongly agree' to 'strongly disagree').

Interval measurement is achieved is the differences are meaningful (e.g. temperature).

Ratio measurement is the highest level – where difference and the absence of a characteristic (zero) are both meaningful (e.g. distance)

## **CROSS TABULATIONS**

Data resulting from observations made on two different related categorical variables (bivariate) can be summarised using a table, known as a two way frequency table or contingency table. The word contingency is used to determine whether there is an association between the variables.

## **CORRELATION**

Correlation

Correlation and regression are two techniques that enable us to determine the connection between the actual dimensions of two or more variables. In this section, we will only look at two variables at a time, but you should be aware that statisticians use these theories and similar formulae to look at the relationship between many variables. When we use these techniques we are concerned with using models for prediction and decision-making. So, how do we model the relationships between two variables?

## **HYPOTHESES TESTS: P-VALUES AND STATISTICAL SIGNIFICANCE**

The traditional approach to reporting a result requires a statement of statistical significance. A p-value is generated from a test statistic. A significant result is indicated with " $p < 0.05$ ". The choice of the value 0.05 as the level of significance is in fact totally arbitrary, but has become enshrined as a standard in statistics.

### **Chi Square Test**

Used for nominal data and ordinal data at a level of significance of 0.05  
Fisher's Test will be used when Chi-square conditions are not met.

### **Multivariate Tests**

To determine the combined effects of variables

## **STATISTICAL SOFTWARE**

SPSS Statistics 24.0 (Released August 2013)

Statgraphics Centurion 15.1 (2006)





**Do you suffer from severe PMS?**

**Or**

**Premenstrual Tension**

**You could be having Premenstrual  
Dysphoric Disorder (PMDD)**

**ISILUMO**



**If you are between the ages of 18 & 35 years you could  
qualify for free treatment in a research study conducted**

@

**DUT-Homoeopathic Day Clinic.**

For more information please contact:  
Ms. Phumza Totongwana (073 865 9873)

## Appendix I: Preparation method for homoeopathic complex



### German Homoeopathic Pharmacopoeia-Preparation for Homoeopathic complex (Method 10)

Preparations according to Method 10 are pillules. They are prepared by transferring a liquid preparation to sucrose pillules (size 3; 110 to 130 pillules weigh 1g), this being done by evenly moistening 100 parts of sucrose pillules with 1 part of liquid preparation. Differences in the mixture ratio are permitted; this difference must be stated on the label. The alcohol content of the liquid preparation should be not less than 60 per cent (m/m), otherwise the final potentisation step of the decimal or centesimal dilution used must be carried out with alcohol 62 per cent (m/m).

Impregnate the pillules (globules, globuli) in a closed vessel, then air-dry. In specific cases granule size 1, 2, and 4 to 10 may be used:

SIZE NUMBER	AMOUNT OF PILLULES	MASS (g)
1	470-530	1
2	220 at 280	1
3	110 at 130	1
4	70 at 90	1
5	40 at 50	1
6	22 at 28	1
7	10	Approximately 1
8	5	Approximately 1
9	3	Approximately 1
10	2	Approximately 1

## Appendix J: Case history form



### Case History Form

Date: \_\_\_\_\_/\_\_\_\_\_/20\_\_\_\_\_

Title:

Surname.....First Name.....

Address (area where patient lives).....

Contact Details: .....

Age.....Gender.....

Marital status S/M/W/D (Please circle one)

Occupation (if unemployed, previous).....

Children: Yes / No

(if yes –include gender & ages))1.....2.....3.....

4.....5.....6.....7.....8.....

*Note:*

- For any symptom: description now, **location, sensation, aetiology, modalities, concomitants, history, treatment/ management** so far.
  - If no symptoms for any section of the case, write **NAD (No Appreciable Disease)** in the space provided.
- 

**1. MAIN COMPLAINT/S:**




**3. CURRENT MEDICINES:** Pharmaceutical or other, including **contraceptive pill/injection, HRT, sleeping tablets.**

Name:	For:

**Current Supplements:** (Vitamins, special drinks etc)

Name:	For:

**4. FAMILY MEDICAL HISTORY:**

<b>MOTHER</b>	<b>FATHER</b>
<b>MOTHER'S MOTHER</b>	<b>FATHER'S MOTHER</b>
<b>MOTHER'S FATHER</b>	<b>FATHER'S FATHER</b>
<b>SIBLINGS</b>	

**5. GASTROINTESTINAL:** Indigestion, heartburn, cramps, flatulence, appetite, cravings and aversions. Aggravations. Thirst.

<b>TYPE OF DRINK:</b>	<b>QUANTITY PER DAY:</b>
How many teaspoons of sugar in tea/ coffee?	How many cups a day?

6. **BOWEL FUNCTION:** Constipation, diarrhea, haemorrhoids (**detail is necessary only if problem is present**).


7. **URINATION:** Frequency, urgency, pain. (**detail is necessary only if UTI is present**). **Males over 40 years of age: strength of stream, stop-start, pain on ejaculation = Prostate.**


8. **MENSTRUATION:** Duration of overall cycle and regularity, duration of menses, volume, colour, consistency, pain, concomitants (e.g. headaches, constipation, diarrhea etc). **Menarche. Pre-menstrual symptoms.** Date of start of last menstrual period. **Pregnancies** – how many [reason for termination], complications, including post-natal depression. **Peri-menopause:** all of the above, as well as symptoms of hot flushes, dry skin, dyspareunia, mood swings. **Menopause:** age of onset. Brief history of menstruation i.e. any problems with menstruation?


9. **GENITALS:** Eruptions, discharge, infections. Females: history of thrush.


10. **SEXUALLY ACTIVITY:** Any problems? Desire/libido? History of **STD's. HIV STATUS? Cd4 Count** if positive. When? **How many partners? Emotions regarding a positive status? Education regarding safe sex.**





11. **CHEST:** Problems with breast, breathing, cardiac.


12. **HEAD:** Ears, eyes, nose, throat/ voice. Headache: **painkillers?** Name, how many, how often? **Issue of medication overuse headache** (= **rebound headache** due to **addiction/dependency**. **Combination ingredient medicines worse than single ingredient medicines**. **Medication overuse** is defined in terms of **treatment days per month**, such that **treatment occurs at least three months**. The headache is present **on more than 15 days per month**.


13. **SLEEP:** Pattern, quality, position. Dreams (only worth pursuing if outstanding/ recurrent dreams)


14. **SKIN:** Current and history, rashes, warts, boils, pimples, easy bruising, rate of healing.


15. **MUSCULOSKELETAL:** Location, modalities, concomitants (e.g. weather changes).


16. **GENERAL:** Energy, weather preferences.


17. **MENTAL:** Ask things that have not already come up in the consultation. **Do not go over that material again unless it seems appropriate to do so.** If you had to **describe yourself**, what **type of person** would you say you are? / What are your **characteristics**? / What is your **personality**? Anxiety / worries, anger, sadness/ depression. **Relationships. What makes you happy?**


**Appendix K: Physical examination form / SOAPE note case summary**



**Physical Examination Form/ SOAPE Note-Case Summary**

**PATIENT DETAILS**

DATE: / / 2015	Patient's name & surname:
----------------	---------------------------

**S MAIN COMPLAINT(S)**

1.	3.
2.	4.

**O ON EXAMINATION**

BP: / mmHg	OBSERVATION (Unusual)
PULSE: bpm	
RESP: bpm	
Temp:	
WEIGHT: kg	
URINE DIPSTICK:	PREGNANCY:

**GENERAL EXAMINATION**

Jaundice	
Anaemia	
Cyanosis	
Clubbing	
Oedema	
Dehydration	
Lymphadenopathy	

**SYSTEM REVIEW**

Respiratory Examination	
Cardiovascular Examination	
Abdominal Examination	
Musculoskeletal Examination	

**A DIAGNOSIS (MEDICAL)**

<b>ICD-10 CODE:</b>	<b>Written Diagnosis:</b>
---------------------	---------------------------

**CENTRE OF THE CASE**

<b>1.</b>	<b>3.</b>
<b>2.</b>	<b>4.</b>

**CASE ANALYSIS**

<b>MENTALS</b>	<b>GENERALS</b>	<b>PARTICULARS</b>

**RUBRICS [3]**


**P**

**REMEDY DIFFERENTIALS**

<b>1.</b>	<b>4.</b>
<b>2.</b>	<b>5.</b>
<b>3.</b>	<b>6.</b>

**PRESCRIPTION**

<b>1.</b>	<b>2.</b>	<b>3.</b>	<b>4.</b>
<b>Rx:</b>	<b>Rx:</b>	<b>Rx:</b>	<b>Rx:</b>
<b>Mitte:</b>	<b>Mitte:</b>	<b>Mitte:</b>	<b>Mitte:</b>
<b>Sig:</b>	<b>Sig:</b>	<b>Sig:</b>	<b>Sig:</b>

**E**

**PATIENT EDUCATION/ADVICE**

<b>1.</b>
<b>2.</b>
<b>3.</b>

**SIGNATURES**

<b>Clinician's Name:</b>	<b>Student's Name: Phumza Totongwana</b>	<b>Dispenser's name:</b>
<b>Clinician's Signature:</b>	<b>Student's Signature</b>	<b>Dispenser's Signature:</b>
<b>Date:</b>	<b>Date:</b>	<b>Date:</b>

## Appendix L: How to take homoeopathic treatment



### How to take Homoeopathic treatment

1. Treatment will be dispensed in a 50ml amber screw top bottle.
2. Participants will be required to take the treatment at least ½ hour before a meal OR ½ an hour after a meal.
3. Participants will be required to take the treatment from 4 days 3<sup>rd</sup> day into the bleed/ menses through the entire 3 cycle period.
3. Open the bottle and take medication as instructed on the label.
4. The dosage is **20 drops** in little water **TWICE** daily.
5. Avoid eating mint, or using camphor (eg. Vicks) whilst on treatment.
6. Store the treatment away from heat, light and electromagnetic radiation (e.g. T.V., computers and cellphones)
7. If drinking coffee, try to wait ½ hour after taking the treatment, before having any.
8. Always take the treatment as instructed/ directed (10 drops sublingually/ under the tongue twice daily)

For any queries regarding your treatment, please Contact the researcher/supervisor(s) of the study:

Ms Phumza Totongwana (20710958)-Researcher 073 865 9873

OR

Dr. J. Ngobese-Ngubane (Supervisor) – 031 373 2484 ([jabulilen@dut.ac.za](mailto:jabulilen@dut.ac.za))

OR

Dr. I. Couchman (Co-supervisor) – 031 373 2482 ([Ingridc@dut.ac.za](mailto:Ingridc@dut.ac.za))




**If it is a new symptom, when did it start, how did it start, and was there any reason?**


**ENERGY:**

**Any change, and if there is how, when and how much?**


**SLEEP:**

Quality: \_\_\_\_\_

Quantity: \_\_\_\_\_

Dreams: \_\_\_\_\_

Other: \_\_\_\_\_

**APPETITE:**

Change: \_\_\_\_\_

New cravings or aversions: \_\_\_\_\_

Thirst: \_\_\_\_\_

**OTHER CHANGES:**

**Has anything else changed since the remedy?**


**MENTALS:**

**How have you been feeling emotionally since the remedy?**






## Appendix N: Permission to use Kessler Psychological Distress scale



### Permission to use Kessler Scale

**Re: Application for permission to use the scale: Kessler Psychological Distress Scale (K10)**

Kessler, Ronald [kessler@hcp.med.harvard.edu]

You forwarded this message on 4/14/2015 1:29 PM.

**Sent:** Tuesday, March 17, 2015 12:02 PM

**To:** Jabulile Cresancia Ngobese

**Cc:** Premchander, Raseeka [Premchander@hcp.med.harvard.edu]

**You have my permission to use the scale. Ron Kessler**

**Sent from my iPhone**

**On Mar 17, 2015, at 4:31 AM, Jabulile Cresancia Ngobese  
<[jabulilen@dut.ac.za](mailto:jabulilen@dut.ac.za)> wrote:**

Dear Professor Kessler.

Thank you for your time reading this e-mail. My name is Dr Jabu Ngobese-Ngubane a homoeopath and lecturer at the Durban University of Technology- South Africa KwaZulu-Natal.

I am currently supervising 3 Master's degree students (Miss Sukati B, Ms Totongwana P and Ms Khumalo Y): **Efficacy of homoeopathic treatment in the management of Premenstrual Dysphoric Disorder (PMDD)**. The study is at a proposal stage. We could will forward you the entire proposal once it is approved by the Research Higher Degrees Committee and Institutional Research Committee.

We would greatly appreciate if you could grant us permission to use the above mentioned scale in our study. The dissertation could also be sent to you on completion.

Looking forward to hearing from you and your team.

Kind regards.

<image002.jpg>

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"This e-mail is subject to our Disclaimer, to view click <http://www.dut.ac.za/disclaimer>"

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## Appendix O: Editing certificate

### **DR RICHARD STEELE**

BA, HDE, MTech(Hom)

**HOMEOPATH**

Registration No. A07309 HM

Practice No. 0807524

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Postal: P.O. Box 30043, Mayville 4058  
Email: rsteel@telkomsa.net

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### **EDITING CERTIFICATE**

**Re: Phumza Virginia Totongwana**

**Master's dissertation: The efficacy of a Homoeopathic complex *Sepia officinalis* 30CH, *Pulsatilla pratensis* 30CH, *Passiflora incarnata* 30CH, *Kalium phosphoricum* 30CH and *Natrum muriaticum* 30CH in the management of Premenstrual Dysphoric Disorder**

I confirm that I have edited this dissertation and the references for clarity, language and layout. I am a freelance editor specialising in proofreading and editing academic documents. I returned the document to the student with track changes so correct implementation of the changes in the text and references is the responsibility of the student. My original tertiary degree which I obtained at the University of Cape Town was a B.A. with English as a major and I went on to complete an H.D.E. (P.G.) Sec. with English as my teaching subject. I obtained a distinction for my M.Tech. dissertation in the Department of Homeopathy at Technikon Natal in 1999 (now the Durban University of Technology). During my 13 years as a part-time lecturer in the Department of Homeopathy at the Durban University of Technology I supervised numerous Master's degree dissertations.

Dr Richard Steele  
23 December 2017  
*per email*