



***The efficacy of a Homoeopathic mother tincture complex  
(Vitex agnus castus, Melissa officinalis and Valeriana  
officinalis) in the management of Premenstrual Dysphoric  
Disorder***

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Dissertation submitted in partial fulfilment of the requirements for the Degree of Master of Technology in Homoeopathy in the Faculty of Health Sciences at the Durban University of Technology.

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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is entirely my own and not of any other person, unless explicitly acknowledged (including citation of published and unpublished sources).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 look to the Mountains; where will my help come from? My help will come from the LORD, who made heaven and earth. Psalms 121.*

This is dedicated to my late mother, Busisiwe Dube, who has been my constant source of inspiration. MAMA, this is for you.

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## Abstract

### Research Problem Statement

Premenstrual dysphoric disorder (PMDD) is a severe form of premenstrual syndrome (PMS) that involves a combination of emotional and physical symptoms that result in significant functional impairment. PMDD can be debilitating and there are multiple treatment options available, but these are not without side effects. Although complimentary or alternative medicine may be beneficial in treating PMDD, however, there is not enough data available to validate their effectiveness. This study aimed at comparing and determining the efficacy of a homoeopathic mother tincture complex (*Vitex agnus castus*, *Melissa officinalis* and *Valeriana officinalis*) compared to placebo in the management of PMDD.

### Methodology

A sample size of 30 consenting female participants with PMDD who met the inclusion criteria as set out in the Diagnostic and Statistical Manual of Mental Disorders. The duration of the study was three months for each participant. Participants were randomly divided into experimental and placebo groups with three consultations over the study period where Kessler Psychological Distress Scale and Visual Analogue Scale were applied. Non-parametric and inferential analysis of data were performed to analyse and compare the effects of treatment and time on symptoms over the three consultation periods ( $\alpha.05$ ).

### Results

Results for both scales showed no statistical significance in the interaction between time and treatment. The results showed no statistical differences between the control and

experimental group in the management of PMDD. However, the mean value measured in the experimental group were consistently lower than the control.

## Conclusion

The conclusion derived from this study is that the homoeopathic complex studied is not effective in the treatment of PMDD. None of the results showed significant differences between the treatment and the placebo group trials. Further studies are highly recommended in this field.

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## List of Acronyms

Acronym	Full Name
DUT	Durban University of Technology
FSH	Follicle Stimulating Hormone
KZN	KwaZulu-Natal
HOM	Homoeopathy
HDC	Homoeopathic Day Clinic
LH	Luteinising Hormone
PMDD	Premenstrual Dysphoric Disorder
PMS	Premenstrual Syndrome
VAS	Visual Analogue Scale



## OPERATIONAL DEFINITIONS

*Adverse effect:* Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product (Stedman and Dirckx 2001).

*Complex:* A combination of a number of things; the sum or total of various things (Mosby's Medical Dictionary 2008).

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

*Efficacy:* The quality of being successful in producing an intended result (Stedman and Dirckx 2001).

*Follicle stimulating hormone:* a hormone synthesised and released by the anterior pituitary gland. Follicle stimulating hormone stimulates ripening of the follicles in the ovary (Oxford Medical Dictionary 2010).

*Homoeopathy:* The word homoeopathy is derived from the words *homoios* meaning “similar” and *pathos* meaning “suffering”. The giving of a similar medicine to treat illness is ancient and predates homoeopathy. It is a science and an art that is based on the realm of modern quantum physics. It is holistic in concept, utilises dietary changes, vitamin therapy, herbalism and psychotherapy. Nevertheless, its holistic approach does not consist of putting together a vast number of different treatments. Homoeopathy is a system of medicine and an alternative approach to treating illness (Bloch and Lewis 2003).

*Holistic:* treatment of the whole being taking into account mental and social factors rather than just a part of the symptoms disease (Cambridge English Dictionary 2017).

*Luteinising hormone*: a hormone synthesised and released by the anterior pituitary gland that stimulates ovulation (Oxford Medical Dictionary 2010).

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

*Menstrual cycle*: The monthly series of changes a woman's body goes through in preparation for the possibility of pregnancy (Mayo Clinic 2017).

*Mother tincture*: Liquid preparations resulting from the extraction of suitable source material in water-ethanol mixtures, which form the starting point for the production of most homoeopathic medicines. Comminution (breaking down into fragments), followed by standard maceration and squeezing techniques are used on fresh plants and succulents, while dried specimens are subjected mainly to percolation with alcohol in a column (Swayne 2000).

*Placebo*: Placebo: a substance that has no therapeutic effect, used as a control in testing new drugs (Oxford Dictionary 2017).

*Placebo effect*: Placebo effect is a genuine psychobiological phenomenon attributed to the overall therapeutic context (Miller and Kaptchuk 2008).

*Placebo group*: a placebo group is 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 (Bloch 2002).

*Posology*: This is the part of medicine concerned with determination of appropriate doses of drugs or agents (Oxford Dictionary 2017).

*Premenstruum*: This is the period or physiological state that immediately precedes menstruation (Sawaran 2001).

*Remedy*: a medicine or treatment for a disease (Oxford Dictionary 2017).

*Side effect*: an effect produced by a drug in addition to its desired therapeutic effects (Oxford Medical Dictionary 2010).

*Signs*: an indication of a particular disorder that is dictated by a physician while examining a patient but is not apparent to the patient (Oxford Medical Dictionary 2010).

*Simillimum*: This is a drug picture most like the clinical picture in the patient. It is arrived at through carefully analysis of information found in the homoeopathic case record (Swayne 2000).

*Symptoms*: an indication of a disease or disorder noticed by the patient himself (Oxford Medical Dictionary 2010).

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

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

## **1.1 BACKGROUND TO THE STUDY**

Premenstrual Dysphoric Disorder (PMDD) is a condition characterised by depressive symptoms, irritability and tension before menstruation. The symptoms of PMDD are more severe than premenstrual syndrome (PMS) (Health Guide 2012), and it affects between 3% and 8% of menstruating women (Htay 2014). Consequently, it is reasonable to assume that thousands of South Africans experience PMDD. This disorder is unlikely to remit without treatment. Symptoms may begin early or may only present later, but findings suggest that they usually persist after onset (Reissman and Lee 2007, Hantsoo and Epperson 2015). Given the chronicity of the disorder, development of new, more effective treatment is crucial.

Htay (2014) states that PMDD is characterised by a depressed or labile mood, anxiety, irritability, anger, and other symptoms occurring exclusively during the two weeks preceding menses. Symptoms may include the following: a decreased interest in usual activities like work, school, friends, and hobbies. Other notable symptoms include: a 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; and a subjective sense of being overwhelmed or out of control (Reissman and Lee 2007).

According to the Diagnostic and Statistical Manual of Mental Disorders (5<sup>th</sup> edition (DSM-V) (American Psychiatric Association 2013), the proposed criteria for PMDD is that the patient has five or more of the above-mentioned symptoms, with at least one symptom related to mood, for most menstrual cycles for at least one year. Moreover, Htay (2014) hinted that physical symptoms such as breast tenderness or swelling, headaches, joint or muscle pain, a sensation of bloating, or weight gain may be experienced. Hence, the need to effectively manage PMDD is highly pertinent for this study.

Homoeopathy is a therapeutic system that holds the ideal of a cure that is rapid, gentle and providing a permanent restoration of health, or removal and annihilation of the disease in its whole extent. One of the hallmark of homoeopathy is that, treatment is accomplish in the shortest, most reliable, and most harmless way, based on easily comprehensible principles stated in Hahnemann's Organon of Medicine (O'Reilly 1996).

Of importance, homoeopathy is based on the *Law of Similars*, and is a system of medical therapeutics that subscribes to fundamental laws of nature. O'Reilly (2001) moots that homoeopathy's curative powers rely on the ability of the body to heal itself using the vital force, which is the life force of all human beings. Interestingly, homoeopathic remedies have no known harmful side effects and are cost effective (National Centre for Complementary and Integrative Health, 2016). This makes it a viable option for treatment. More so, homoeopathic medicines are safe to take during pregnancy, menopause and infancy. Menstrual disorders at all ages and stages can be effectively with homoeopathy (Bloch and Lewis 2003).

According to Rafieian and Movahedi (2017), *Vitex agnus castus* is a useful phytotherapeutic herb that treats PMS and PMDD. They alleged that *Vitex agnus castus* is highly beneficial in postmenstrual cases and helps to treat infertility in men and women. More so, *Vitex agnus castus* were use in medieval times, particularly as herbs to treat gynaecological disorders such as depression due to hormonal imbalance; fibroids; amenorrhea; irregular bleeding; spotting; cystic hyperplasia of the womb lining; and distension cause by hormonal changes during the menstrual cycle (Gardiner 2000).

Loch, Selle and Boblitz (2000) conducted a study on PMS and treatment with a phytopharmaceutical formulation containing *Vitex agnus castus*. Participants answered a questionnaire on psychic and somatic complaints related to PMS, and on the four characteristic symptom complexes associated therewith, namely, depression, anxiety, craving and hyper-hydration. After treatment, 93% showed a decrease in overall symptoms, while 1.2% reported minor side effects. The above reports suggests that the

herb may have positive effects on the psychosomatic aspects associated with PMDD, and this needs to be further investigated.

Apart from *Vitex agnus castus*, the use of *Melissa officinalis*, and *Valeriana officinalis* have been particular important in complementary and alternative medicine. Houghton (1999) revealed that *Valeriana officinalis* is a medical plant used in complementary and alternative medicine for its sedative and anxiolytic properties. He noted that the herb has been used to treat hot flushes in menopausal women, to improve memory and to improve sleeping patterns. It is one of the oldest recorded healing plants use in Egypt, Europe, Greece and China. The plant has been associated with reducing sleep disorders (Bent *et al.* 2006).

With reference to *Melissa officinalis herb*, Blumenthal, Goldberg and Brickmann (2000) noted that the herb commonly referred to as lemon balm is use for the relief of stress-induced headaches, as a mild sedative and as an antiviral agent in the treatment of herpes simplex.

Despite the above-mentioned usefulness and importance of these herbs, the current medical treatment for PMDD still heavily rely on antidepressant. Concerning, Lliades (2013) pointed out that antidepressant have numerous unpleasant side effects, some of which continue even when the antidepressants are discontinued in the form of withdrawal-like symptoms. This research therefore aimed to investigate whether a homoeopathic complex would be beneficial in the treatment of PMDD.

## **1.2 Aim of the study**

The study aimed to compare and determine the efficacy of a homoeopathic mother tincture complex (*Vitex agnus castus*, *Melissa officinalis* and *Valeriana officinalis*) to a placebo in the management of Premenstrual Dysphoric Disorder (PMDD) by means Kessler Psychological Distress Scale and Visual Analogue Scale

## **1.3 Objectives of the study**

The objectives of this study is as follows:

#### *1.3.1 The first objective:*

The first objective was to determine the efficacy of a homoeopathic mother tincture complex (*Vitex agnus castus*, *Melissa officinalis* and *Valeriana officinalis*) to a placebo in the management of Premenstrual Dysphoric Disorder (PMDD) by means of Kessler Psychological Distress Scale.

#### *1.3.2 The second objective:*

The second objective was to determine the efficacy of a homoeopathic mother tincture complex (*Vitex agnus castus*, *Melissa officinalis* and *Valeriana officinalis*) to a placebo in the management of Premenstrual Dysphoric Disorder (PMDD) by means of Visual Analogue Scale.

#### *1.3.3 The third objective:*

The third objective was to compare the effectiveness of the two groups (Treatment group and Placebo group) with each other with regard to the two measurement tools.

### **1.4 Statement of null hypotheses**

#### *1.4.1 The first hypothesis:*

It was hypothesized that homoeopathic mother tincture complex would have no beneficial effect in the management of Premenstrual Dysphoric Disorder (PMDD) by means of the Kessler Psychological Distress Scale and Visual Analogue Scale.

#### *1.4.2 The second hypothesis:*

It was hypothesized that Placebo would have no beneficial effect in the management of Premenstrual Dysphoric Disorder (PMDD) by means of the Kessler Psychological Distress Scale and Visual Analogue Scale.

#### *1.4.3 The third hypothesis:*

It was hypothesized that would be no difference in effect between the two groups in in the management of Premenstrual Dysphoric Disorder (PMDD).

Although great stride has been achieved in understanding and diagnosis PMDD, there is, however, limited studies targeting the development of pharmacological treatment of the disorder. As such, and as highlighted in the report of European Medicines Agency (2011) clinical studies are required for the management of PMDD. From the perspective of homoeopathic, Klein-Laansma and Jong (2014) advocate for more homoeopathic research in the field of PMDD. Hence, this research aimed to investigate whether a homoeopathic mother tincture complex with *Vitex agnus castus*, *Mellisa officinalis* and *Valeriana officinalis* is beneficial in the treatment of PMDD.



## **CHAPTER TWO: LITERATURE REVIEW**

This chapter review literature related to the use of pharmacological remedy in the treatment and management of Premenstrual Dysphoric Disorder. The review introduces PMDD and explains the theories of aetiology associated with the disorder. Subsequently, the epidemiology, pathophysiology, signs and symptoms, and diagnosis will be discussed. Overall, this literature review is structured into ten sections. Section one explains the meaning and concept of PMDD. Section two discusses the theories of aetiology. Section three looks at the epidemiological trends of the disorder. Section four examines the pathophysiological pattern associated with the PMDD. Section five described the signs and symptoms of PMDD. A discussion follows on methods of diagnosing PMDD. It is envisaged that understanding the methods of PMDD diagnoses, particularly with the use of both Visual analogue scale and Kessler psychological distress scale will help identify the disorder in women suffering from PMDD. This chapter concludes with the evaluation the different methods of treating PMDD, particularly as it a critical factor in introducing and promoting homoeopathic treatment options.

### **2.1 Overview of Premenstrual Dysphoric Disorder**

The premenstrual dysphoric disorder is defined as a severe form of PMS. PMDD's profile, characterized by cognitive-affective symptoms during the premenstruum, is unique from that of other affective disorders in its symptoms and cyclicity. The premenstrual dysphoric disorder is a condition in which a woman has severe depression symptoms, irritability, and tension before menstruation. The symptoms of PMDD are more severe than those seen with PMS. Premenstrual Dysphoric Disorder affects between 3% and 8% of women during the years when they are having menstrual periods (Htay 2014). Despite the prevalence of PMDD, little is known of its natural course. More so, the data obtained from cross-sectional, retrospective, or epidemiologic analyses or randomized clinical studies may be subject to limitations. Given the chronicity of the disorder, development of new, more effective treatment is crucial. Recently designated as a disorder in the DSM-5, premenstrual dysphoric disorder (PMDD) presents an array of avenues for further research.

### 2.1.1 Definition

Hantsoo and Epperson (2015) state that defining PMDD, mood symptoms are key. The woman may also experience difficulty concentrating or a sense of feeling overwhelmed or out of control.

## 2.2 Theories of the aetiology of PMDD

The aetiology of PMDD is an active area of investigation. Potential biological contributors include central nervous system (CNS) sensitivity to reproductive hormones, genetic factors, and psychosocial factors such as stress. The timing of symptom onset and offset in PMDD suggests that hormonal fluctuation is a key component in PMDD's pathogenesis. Paradoxically, women with PMDD cannot be distinguished from asymptomatic women in terms of peripheral ovarian hormone levels. Instead, recent research suggests that women with PMDD have altered sensitivity to normal hormonal fluctuations, particularly oestrogen and progesterone, neuroactive steroids that influence CNS function (Hantsoo and Epperson 2015).

### 2.2.1 Serotonin levels

A growing body of evidence suggest that serotonin (5 hydroxytryptamine / 5-HT) may be important in the aetiology of PMDD. According to Htay (2014) the fluctuation of normal hormones during the menstrual cycles causes deficiency in the neurotransmitter serotonin. Of interest, neurotransmitter such as serotonin found mainly in the brain, intestines, lungs, and blood platelets act like hormones. High levels of serotonin can cause excessive nerve activity, headaches, restlessness, confusion, nausea, and loss of muscle coordination (Mayo clinic 2018).

### 2.2.2 Absence of Progesterone

Premenstrual dysphoric disorder occurs when there is decreased/absent levels of progesterone. Progesterone is produced in the ovaries following ovulation every month. It helps maintain the uterine lining in case of pregnancy and, if there is no fertilised egg present, the level of progesterone drops and menstruation starts. Symptoms of absent progesterone include loss of libido, depression, hot flushes, irregular menses and

headache. Brauser (2013) noted that the variation of progesterone levels coincides with the onset and relief of PMDD (Brauser 2013). Despite this revelation, Stoppler (2017) recently reported that there is limited understanding in the exact mechanism by which hormones interact to cause PMDD.

### 2.2.3 Other Causes

Recent research shows that some women inherit a gene that raises the risk of PMDD. Notwithstanding this, Lobo and Pinkerton (2010) disclosed that undiagnosed anxiety or depression problem also causes PMDD. Resonating further, Hantsoo and Epperson (2015) in their asserted view, highlights that there is an association with known history of stress and PMDD disorder.

## 2.3 Epidemiology of PMDD

Halbreich *et al.* (2003) estimated that 3-8% of women of reproductive age meet strict criteria for premenstrual dysphoric disorder (PMDD). It is further noted that assessment of published reports demonstrate that the prevalence of clinically relevant dysphoric premenstrual disorder is probably higher. 13-18% of women of reproductive age may have premenstrual dysphoric symptoms severe enough to induce impairment and distress, though the number of symptoms may not meet the arbitrary count of five symptoms on the PMDD list. The impairment and lowered quality of life for PMDD is similar to that of dysthymic disorder and is not much lower than major depressive disorder (Halbreich *et al.* 2003).

PMDD is still under-recognized in large published epidemiological studies, as well as assessments of burden of disease. The burden of PMDD as well as the disability-adjusted life years (DALY) lost due to this repeated-cyclic disorder is in the same magnitude, as other major recognized disorders. Appropriate recognition of the disorder and its impact should lead to treatment of more women with PMDD (Halbreich *et al.* 2003).

According to Yonkers, Robert and Casper (2017), estimates as high as 80% prevalence rate have been reported for PMS, based upon the inclusion of women who have any form

of premenstrual mood or physical symptoms. These estimates do not consider whether symptoms are moderate to severe or if they interfere with functioning. When one applies strict inclusion criteria for PMDD, several studies (Rivera and Frank 1990; Soares *et al.* 2001; Gehlert *et al.* 2009) that made use of prospective ratings to determine diagnosis, reported an estimate around 2 %.

## **2.4 Pathophysiology of PMDD**

Walsh (2015) states that research is yet to find a conclusive pathophysiological explanation for PMS and PMDD. Early theories thought there were abnormalities in ovarian sex steroid levels. However, these theories is now been disapproved, as no differences have been demonstrated between symptomatic and asymptomatic women. Moreover, no study has demonstrated differences in progesterone levels. It is generally recognised that aetiology is centred on the ovarian cycle, and this theory is supported by the lack of symptoms before puberty, during pregnancy, after menopause, and during treatment with gonadotrophin-releasing hormone (GnRH) analogues (Walsh 2015).

According to O' Brian *et al.* 2001 sex steroids easily pass the blood–brain barrier, and their receptors are abundant in many areas of the brain including the amygdala and hypothalamus. It is hypothesised that progesterone is metabolised in the brain to allopregnanolone and pregnanolone, which stimulates the gamma-aminobutyric acid (GABA) inhibitory neurotransmitter system (Walsh 2005).

GABA receptors are associated with alterations in mood, cognition, and affect. In high concentrations, pregnanolone and allopregnanolone produce anxiolytic, sedative and anaesthetic effects. However, at lower levels, allopregnanolone can cause anxiety, negative mood and aggression. The GABA receptors become less sensitive to allopregnanolone after exposure to high concentrations, and hence, the worsened symptoms experienced during the luteal phase (Spinelli 2004).

Premenstrual syndrome (PMS) and premenstrual dysphoric disorder (PMDD) are triggered by hormonal events ensuing after ovulation. The symptoms can begin in the

early, mid or late luteal phase and are not associated with defined concentrations of any specific gonadal or non-gonadal hormone. Although evidence for a hormonal abnormality is yet to be established, the symptoms of the premenstrual disorders are related to the production of progesterone by the ovaries (Rapkin and Akopians 2012).

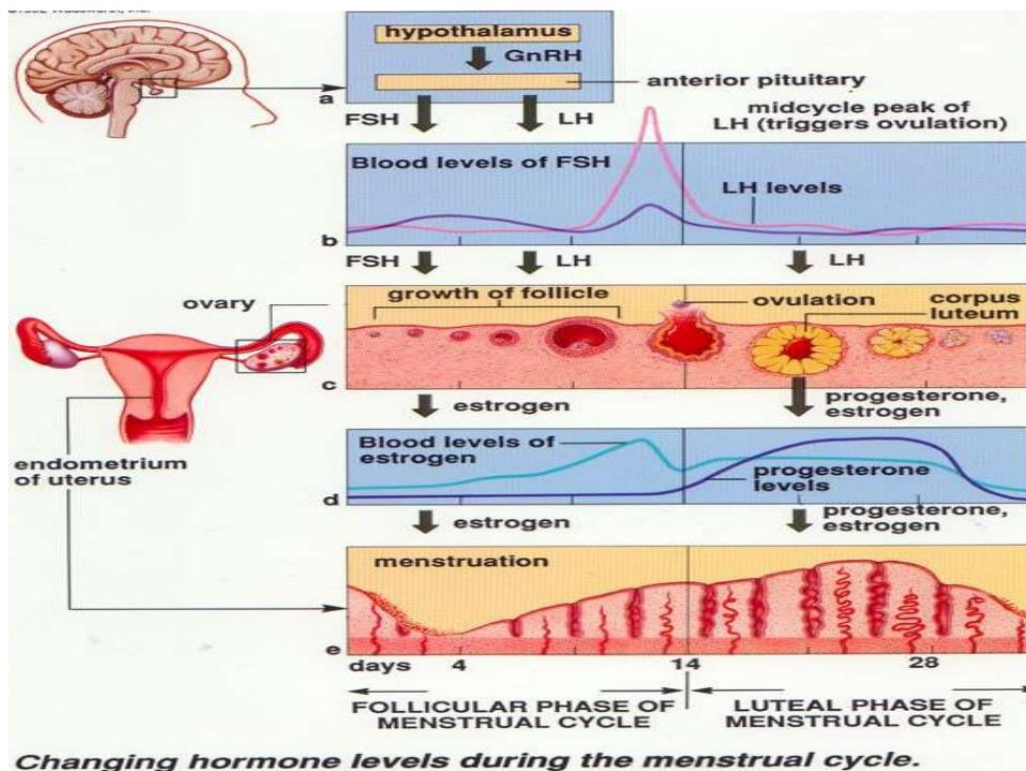
The two best-studied and relevant neurotransmitter systems implicated in the genesis of the symptoms are the GABAergic and the serotonergic systems. Metabolites of progesterone formed by the corpus luteum of the ovary and in the brain bind to a neurosteroid-binding site on the membrane of the gamma-aminobutyric acid (GABA) receptor, changing its configuration, rendering it resistant to further activation and finally decreasing central GABA-mediated inhibition. The lowering of serotonin can give rise to PMS-like symptoms and serotonergic functioning seems to be deficient by some methods of estimating serotonergic activity in the brain (Rapkin and Akopians 2012).

## **2.5 Signs and symptoms**

According to the DSM-V (American Psychiatric Association 2013) the major symptoms of PMDD are mood swings, depressed mood or feelings of hopelessness, marked anger, increased interpersonal conflicts, tension and anxiety, irritability, decreased interest in usual activities, difficulty concentrating and fatigue.

Gallenberg (2012) further states that sleep disturbances, increased or decreased appetite, breast tenderness or breast pain, bloating and headache may be present.

Symptoms of PMDD are not only physical, but they are also psychological as well as behavioural. Understanding what the symptoms are – whether physical, psychological or behavioural – will help in finding ways to alleviate the associated symptoms of PMDD and PMS.



**Figure 2. 1: Changing hormone levels during the menstrual cycle**  
Adapted from Nitin (2012).

Figure 2.1 shows the two major phases of menstruation, the follicular phase and the luteal phase. Ovulation occurs between the phases. The hypothalamus, the anterior pituitary gland and the ovaries influence the phases. The follicular phase begins on the day of menstruation until ovulation and continues again after that the luteal phase (Reissman and Lee 2007). The anterior pituitary gland secretes follicle stimulating hormone (FSH) and luteinising hormone (LH) in response to the gonadotropin-releasing hormone secreted by the hypothalamus. Increase in the FSH causes development of follicles, which will eventually release an oocyte during the cycle. The follicles secrete estradiol and inhibit which also act on the hypothalamus causing negative feedback decreasing the level of FSH and stopping the development of the follicles. As the level of oestradiol increases, the endometrium lining is formed and the anterior pituitary releases a surge of LH, which matures the follicle, and formation of the corpus luteum, which synthesises

progesterone. Progesterone maintains the lining ready for fertilisation and causes a negative feedback of FSH and LH. If fertilisation does not occur the corpus luteum decreases the progesterone levels and the cycle begins again (Dipiro *et al.* 2002). According to Brauser (2013) PMDD may have an increased sensitivity to this particular hormone (progesterone) activity and experience increased activity in the emotional center of the brain.

**Table2. 1 Symptoms associated with Premenstrual Syndrome and Premenstrual Dysphoric Disorder**

Physical	Psychological and Behavioural
Abdominal bloating	Anger, irritability
Body aches	Anxiety
Breast tenderness and/or fullness	Changes in appetite (overeating or food cravings)
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"

Adapted from American Family Physician (2011)

## 2.6 Diagnosis of PMDD

Htay (2014) states that the initial steps in evaluating a patient for PMDD is aimed at excluding organic syndromes with manifestations similar to the disorder such as thyroid disorder, perimenopause, menopause and anaemia. According to his report, the DSM-IV and DSM-V diagnoses is based upon a perimenstrual pattern of at least five of 11 cognitive-affective, behavioural and physical symptoms, and at least one of the key affective symptoms of affective lability (mood swings, tearfulness, sensitivity to rejection); irritability or anger that is often characterised by increased interpersonal conflicts; marked depressed mood, hopelessness, or self-deprecating thoughts; or anxiety, and tension or feeling on edge.

Diagnosis is actualise based upon the symptoms listed in Table 2.1, and their severity and their level of interference with a woman's life. A woman must experience at least five of the 11 symptoms listed in Table 2.1, as per DSM-V (American Psychiatric Association 2013) (Appendix F).

A written record of symptoms is used to track symptoms and detect patterns of a possible PMDD diagnosis. This diagnosis can be made after two consecutive symptomatic cycles. A calendar-like chart with listed symptoms experienced will be a good gauge to determine any pattern emerging and subsequently used to determine a diagnosis. This approach is used to decide if the symptoms are related to PMDD or PMS (Biggs and Demuth 2011). Table 2.2 is a depiction of criteria used to diagnose possible symptoms of PMDD. Women experiencing at least five of these symptoms have a high probability that they could be experiencing PMDD.

**Table2. 2 Diagnostic research criteria for Premenstrual Dysphoric Disorder**

Diagnostic research criteria for Premenstrual Dysphoric Disorder
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).

Adapted from DSM-V (American Psychiatric Association 2013)

## 2.7 Differential diagnoses

The previous section has highlighted the method of diagnosing PMDD. This section divers into the different forms of disorder with a view of gaining comprehensive understanding of PMDD disorder.

### 2.7.1 Premenstrual Syndrome (PMS)

Both PMS and PMDD are associated with recurring, uncomfortable, predictable symptoms that begin in the luteal phase of the cycle and resolve shortly after the onset of the period (Reissman and Lee 2007). Common physical symptoms include breast tenderness, abdominal bloating and headache. Mental and or emotional symptoms include depression, angry outbursts, anxiety, social withdrawal and irritability. The severity of symptoms is judged according to the degree of interference with day-to-day activities and relationships. The American College of Obstetricians and Gynaecologists (ACOG) (2001) have outlined the method of diagnosis PMS. These includes at least one or more of each of the mental/emotional (depression, angry outburst, irritability, anxiety, confusion and social withdrawal) and physical symptoms (breast tenderness, headache, swelling of extremities, and abdominal bloating).

The ACOG documents highlights that the PMS symptoms occur during the five days before menses in each of the previous three menstrual cycles. It is relieved within four days of the onset of menses, and not recur until at least day 13 of the next cycle.

Diagnosis typically involves the daily charting of symptoms over two or more cycles. The most commonly reported symptom associated with PMS is irritability (Mishell 2005). PMDD represents the most severe and disabling end of the spectrum of premenstrual disorders.

#### 2.7.2 Major depressive disorder

The major depressive disorder is defined as a state of low mood and lack of interest in activity (Kennedy 2008). Moreover, different people are affected by depression in different ways. The most common symptoms of depression include physical symptoms such as headaches, backache, indigestion and constipation. Mental symptoms include depressed mood, guilt, loss of interest in activities, suicidal thoughts as well as concentration problems (Colledge *et al.* 2010). PMDD causes severe impairment in quality of life equivalent to major depressive disorder that continually cycles on a monthly bases (Girdler 2010).

#### 2.7.3 Chronic fatigue syndrome

Chronic fatigue syndrome is characterised by extreme tiredness that does not go away even with rest that cannot be explained by any underlying condition and is referred to as *myalgic encephalomyelitis* (Mayo Clinic 2016). Although the tiredness may come with any amount of activity, what is, however, unique about the symptom is that rest does not ameliorate it. The disorder has six official signs and symptoms, which include fatigue, loss of memory, sore throat, unexplained muscle pain, enlarged cervical and axillary lymph nodes, and pain that moves from one joint to another without swelling or redness.

#### 2.7.4 Bipolar affective syndrome

A bipolar affective syndrome is a serious lifelong struggle and challenge characterised by prolonged and profound depression that alternates with mania (irritable mood). Mania lasts at least one week (Sorreff 2016). PMDD has a minimum of two manic and the main indicator being whether or not this episode occur on days between ovulation and onset of the period only (Gia Allemand Foundation 2012).

#### 2.7.5 Dysthymic disorder

Dysthymia is a chronic type of depression that last for two years. It is mild and can affect one's function at school, work or home and it appears to be more common in females. Most people with dysthymic disorder cannot tell when they first became depressed. Symptoms may cause significant impairment and may include poor appetite or overeating, sleep problems, feelings of hopelessness, irritability or excessive anger and low self-esteem. Everything is an effort and nothing is enjoyable (American Academy of Family Physicians 2017).

#### 2.7.6 Polycystic Ovarian Syndrome

Polycystic ovarian syndrome is the most common endocrine disorder affecting productive aged women .There is no universally accepted definition for Polycystic Ovarian Syndrome. It is; however, believe that 7% to 8% of the reproductive aged female population is living with this condition. It is characterised by obesity, elevated levels of testosterone, infertility and chronic anovulation (Duncan 2014).

#### 2.7.7 Hyperprolactinemia

Hyperprolactinemia is a condition characterised by excessive prolactin. Prolactin is the hormone responsible for breastmilk production. This hyper-secretion can be due to medication, pregnancy, prolactin secreting tumours or a pituitary tumour. The first sign is amenorrhea, although symptoms vary from person to person. In women, symptoms include amenorrhea, breast milk secretion, infertility and decreased libido (Kumar *et al.* 2007).

#### 2.7.8 Hypothyroidism

Hypothyroidism is a common endocrine condition that occurs when there is interference with the production of adequate levels of the thyroid hormone. (Dudhia and Dudhia (2014) noted that hypothyroidism is divided into primary and secondary categories depending on whether the problem comes from the thyroid gland or the hypothalamus or pituitary

disease. People with hypothyroidism often have no/moderate symptoms related to the underlying cause. In general, problems tend to develop slowly, often over a number of years (Colledge *et al.* 2010). Signs and symptoms include coarse skin, cold intolerance, and bradycardia, but may also include fatigue, prolonged jaundice, cretinism and myxoedema (Porter 2011). According to Moore (2002), PMDD and hypothyroidism may share some symptoms however the diagnosis of hypothyroidism is easily confirmed with a blood test, while PMDD is based on clinical diagnosis.

#### 2.7.9 Hyperthyroidism

Hyperthyroidism is a condition in which the thyroid overproduces the thyroid hormone. Hyperthyroidism is caused by excess iodine, thyroiditis, medication, benign tumours of the thyroid or the pituitary, or tumours of the ovaries. Symptoms associated with hyperthyroidism include hyper-metabolic state (rapid heart rate, hand tremors, elevated blood pressure), heat intolerance, increased or decreased appetite, loss of weight or even weight gain, and nervousness (Marcin 2016).

#### 2.7.10 Endometriosis

Endometriosis is the presence of endometrial glands and stroma tissue outside the uterus. This anomaly could be found mainly in women of reproductive age (Leyland *et al.* 2010). It may involve ovaries, fallopian tubes and other pelvic tissues but rarely spreads beyond the pelvic organs (Mayo Clinic 2016). Common symptoms of endometriosis include pelvic pain, dysmenorrhoea, dyspareunia, bleeding, diarrhoea, lower back pain and constipation (Mayo Clinic 2016). Pain starts several days before the menses and continues through the first few days. This disorder becomes chronic and pain could occur at times unrelated to the menstrual period (Beers and Berkow 1999).

### 2.8 Assessment methods or measurement tools

In attempting to effectively diagnose PMDD, the use of Visual Analogue Scale and Kessler Psychological Distress scale is highly relevant for accurate assessment of PMDD disorder. The section therefore presents a review on the applications of these two scales.

### 2.8.1 Visual Analogue Scale

This study uses a VAS as one of the measuring instruments (see Appendix B). A VAS is a measurement instrument that tries to measure a characteristic or attitude that is believed to range across a continuum of values. These values are not easily 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, their pain does not take discrete jumps, as a categorisation of none, mild, moderate, and severe would suggest. It was to capture this idea of an underlying continuum that the VAS was devised (Crichton 2001).

Operationally a VAS is usually a horizontal line, 100 mm long. As such, an assessment is clearly highly subjective; these scales are of most value when looking at change within individuals (Crichton 2001). Steiner (1999) used VAS as a measurement of PMS and concluded that VAS was a low burden to the patient, and was reliable, valid and sensitive to change. Other studies have also applied the use of this scale effectively (Berger *et al.* 2000; Bodian *et al.* 2001; Teleman 2005; Kent 2005; Ramoupi 2012).

### 2.8.2 Kessler Psychological Distress Scale

The Kessler Psychological Distress Scale is a 10-item 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 (See Appendix C). The use of a patient self-report measure is a desirable method of assessment, because, it is a genuine attempt on the part of the clinician to collect information on the patient's current condition and to establish a productive dialogue (Andrews and Slade 2001). This scale is enough to detect the change in the condition over a period.

## 2.9 Treatment of PMDD

PMDD is an important public health concern affecting more young women than the old. This section will review some of the different treatments available in the management of PMDD. It will explore the use of homoeopathic treatment, as an alternative treatment option for PMDD.

### 2.9.1 Medical treatment for PMDD- Selective serotonin-reuptake inhibitors (SSRI)

According to Stöppler (2013), the first option is usually antidepressants known as selective serotonin-reuptake inhibitors (SSRI). These medications work by regulating the levels of the neurotransmitter serotonin in the brain. Selective serotonin-reuptake inhibitors that have shown to be effective in the treatment of PMDD include fluoxetine (Prozac, Sarafem), sertraline (Zoloft), paroxetine (Paxil), and Citalopram (Celexa). Up to 75% of women report relief of symptoms when treated with SSRI medications. Stöppler (2013) refers to the increased alleviation of PMDD by the use of SSRIs. Harvard Mental Health Letter (2009) reiterate the importance of assessment of the most suitable medication for the alleviation of PMDD, referring to the SSRIs as well as Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs) such as venlafaxine (Effexor), and tricyclic antidepressants such as clomipramine (Anafranil). Luisi and Parasauskas (2003) noted some adverse effects of taking SSRIs such as anxiety, fatigue, headaches and insomnia. Decreased libido and anorgasmia were also observed amongst women with PMDD. The potential hazard is a development for dependency. Numerous drug interaction with SSRI agents can also pose a problem for patients taking other agents that are highly protein bound such as warfarin, theophylline, barbiturates and benzodiazepines (Lacy 2004).

### 2.9.2 Antidepressants

Antidepressants have numerous unpleasant side effects. Even when the antidepressants are discontinued, they may cause withdrawal-like symptoms (Llides 2013). The common side effects are cardiovascular effects, muscle tremors, and weight gain (which alone predisposes a person to other health disorders). This could also cause blurred vision, restlessness, and changes in sugar concentrations (Swart and Dreyer 2007).

### 2.9.3 Hormone therapy

Hormone therapy treatments are used in cases where there is a hormone deficiency. Supplementing progesterone hormone is a common treatment for PMDD, but there is not sufficient evidence to conclude that a deficiency of progesterone exacerbates PMDD (Harvard Mental Health Letter, 2009). This therefore makes this option ineffectual. Pick

(2015) states that it is good for all women to have their progesterone levels tested. She asserts that this measure would be a good barometer to determine whether prescribed progesterone pills should be taken in lieu of contraceptives and antidepressants.

#### 2.9.4 Oral contraceptives

Oral contraceptives are widely known for acting as a stabiliser for reproductive hormones. Even though they are used in the alleviation of PMDD, no separate studies have been conducted to ascertain the effectiveness of oral contraceptives in the treatment of PMDD and its associated symptoms. A contraceptive called YAZ composed of ethinyl estradiol with drospirenone is reported to be effective in treating both emotional and physical symptoms associated with PMDD (Reissman and Lee 2007). Pick (2015) cites other contraceptives that could be used for reducing the effects of PMDD. These contraceptives include; Ortho Tri-Cyclen and Ortho Tri-Cyclen Lo, as well as Mircette and NuvaRing. Using this method to alleviate the symptoms of PMDD does not provide long-term solutions and is a disadvantage as it temporarily blocks the symptoms. It could even make the situation worse over time. Using this method of reprieve is only temporary and should not be thought of as a permanent solution to the relief of symptoms associated with PMS and PMDD.

#### 2.9.5 Oestrogen

Using oestrogen to inhibit ovulation may be a possible treatment for PMDD. According to the Harvard Mental Health Letter (2009), inhibition of ovulation could be achieved by means of a skin patch or using a subcutaneous implant. They assert that oestrogen and progesterone should be taken concurrently to reduce any risk of uterine cancer.

#### 2.9.6 Exercise

According to Daley (2009), exercise has been noted to “reduce the severity of PMS and primary dysmenorrhoea”. The author further notes that even though it reduces menstrual pains, there is no evidence of its effectiveness. Jarvis *et al.* (2008) corroborates this assessment, stating that even though no studies have been conducted regarding exercise

reducing PMDD, lifestyle modifications are the first recommendation for all women with PMS/PMDD and may be all that is needed to treat mild to moderate symptoms.

#### 2.9.7 Supplements

Supplements can be used to reduce symptoms of PMDD. No previous studies have been conducted to provide any long-standing evidence that they can regulate the symptoms of PMDD. Supplements such as calcium, magnesium, vitamin E, vitamin B2 can be used to reduce some of the pressing symptoms associated with PMDD. A recommended dosage of 1200mg of calcium a day (during the week preceding PMDD and in the same week) was reported to reduce mood swings associated with PMDD and PMS. Vitamin E also plays a role in reducing symptoms. Magnesium helps in reducing bloating in the stomach as well as relieving breast tenderness (Massachusetts General Hospital 2015).

#### 2.9.8 Light therapy

According to the Massachusetts General Hospital (2015) report, light therapy has also been explored as a possible treatment for PMDD. The report reveal that the effect of light therapy appears to be modest for this modality, although, further studies needs to be exploited to determine whether this may be effective and well tolerated option for some women.

#### 2.9.9 Other treatments for PMDD

Gallenberg (2012) states that treatment of PMDD is directed at preventing or minimising symptoms and may include birth control pills, nutritional supplements, diet, lifestyle changes, regular exercise, cutting back caffeine, eating carbohydrates in small portions, more frequent meals and avoiding emotional triggers. Grohol (2009) further states that psychotherapy can help a woman learn to better cope with the symptoms and with other challenges in her life. Therapy can also teach stress reduction techniques, meditation and relaxation exercises that help many women better face the symptoms of PMDD.



## **2.10 Homoeopathy**

Homoeopathy is a holistic practice of medicine that aims to treat the person in totality. The word totality encompasses symptoms, pathology, personality, trauma and inherited tendencies and individual tendencies (Van Wyk 2009). Homoeopathic medicine works by stimulating the body's inherent ability to heal itself (Trivieri 2001). The German physician and chemist Samuel Hahnemann (1755-1843) developed homoeopathy in 1796. It is based on the Law of Similars 'Like cures like' which states that in order to cure a disease, one must look for medical substances that can create similar symptomatology in a healthy body (Dancu 1996; Vithoulkas 2009).

Homoeopathy is a therapeutic system that holds the ideal of a cure that is rapid, gentle and results in a permanent restoration of the health, or removal and dissolution of the disease in its whole extent, in the shortest, most reliable, and most harmless way (Kunja 2012). In homoeopathy, illness is understood as a multi-dimensional phenomenon, brought on by an internal disturbance that manifests in each person in a uniquely characteristic way. These individual characteristics are the result of many different factors, including heredity, life experiences, life style and the kind of interventions a patient has had for their condition. De Schepper (2001) states that homoeopathy is a gentle, deeply-healing system which uses healing substances so diluted that they do not cause side effects like conventional pharmaceuticals, which can suppress symptoms that can later reoccur (often on a deeper level). Homoeopathy cures 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.

De Schepper (2001) postulates that homoeopathy does not cause side effects and that it enhances the quality of life as it heals. It works 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 and not just the disease or symptoms (Kent 2005). Yakir *et al.* (2001) state that homoeopathy is highly controversial, mainly because of the poor understanding of its mode of action. Due to the limited number of controlled clinical trials, it is difficult to assess the efficacy.

However, Danno *et al.* (2013) conducted a study of cases involving homoeopathic treatment of PMS, and found randomised placebo-controlled trials where homoeopathic medicines appeared to be effective in reducing PMS symptoms.

#### 2.10.1 The efficacy of homoeopathy on PMDD

According to Chevallier (2007), *Vitex agnus castus* is known to have progesterone-like effects within the body, acting on the pituitary gland to improve menstrual regularity. It helps relieve menstrual symptoms such as fluid retention, headaches, breast tenderness, and premenstrual tension. Loch, Selle and Boblitz (2000) investigated PMS in relation to psychic and somatic complaints and the four characteristic symptom complexes of depression, anxiety, craving and hyper-hydration. They used a phytopharmaceutical formulation containing *Vitex agnus castus*. Ninety three percent of patients reported a decrease in the number of symptoms and 94% assessed the *Vitex agnus castus* treatment as beneficial. The risk/benefit ratio is rated as good with significant efficacy for all aspects of the multifaceted clinical picture of PMS, with a safe profile comparable to other *Vitex* preparations.

Klein-Laansma and Jong (2014) call for more research in the field of homoeopathic treatment of premenstrual disorders. They state that the challenge for the research community is to provide convincing evidence for specific homoeopathic treatments which achieve reproducible clinical results and which are also easy to implement via existing public healthcare systems. Hence, this study will contribute clinical evidence for the homoeopathic treatment of women with premenstrual disorders. This will urge more women to use homoeopathic treatments that have very little to no side effects, as opposed to medical treatment options that have side effects.

#### 2.10.2 The homoeopathic mother tincture complex

##### 2.10.2.1 Mother tincture

A mother tincture is a botanical extract with a specific amount of alcohol. In general, a mother tincture contains the lowest possible potency of any particular homoeopathic

preparation. A mother tincture is the first stage in the preparation of a homoeopathic remedy dilution. Mother tinctures could be use as treatment options because they have fast action within minutes and because they remain effective for a long time. In addition, Brighton (2013) noted the body, especially the gastrointestinal system, easily accepted mother tinctures.

Mother tinctures for homoeopathic preparations are liquid preparations obtained by the solvent action of a suitable vehicle upon raw materials. The raw materials are usually in the fresh form but may be dried. Mother tinctures for homoeopathic preparations can also be obtain from plant juices, with, or without the addition of a vehicle. For some preparations, the matter that for extraction may undergo a preliminary treatment (Brighton 2013).

Tinctures are prepared by maceration, digestion, infusion, decoction, and fermentation or as described in the individual monographs, usually using alcohol of a suitable concentration. Mother tinctures for homoeopathic preparations are obtain using a fixed proportion of raw material to solvent, taking the moisture content of the raw material into account, unless otherwise justified and authorised. If fresh plants are used, suitable procedures are to be adhered to ensure freshness. The competent authorities may require that the freshness be establish by means of a suitable test (Brighton 2013). The homoeopathic mother tincture complex used in this study contained *Vitex agnus castus*, *Mellisa officinalis* and *Valerian officinalis*. The rationale for its use are discuss below.

#### 2.10.2.2 *Vitex agnus castus*

*Vitex agnus castus* has an effect on hormones that regulate women's reproductive cycles. It is used for menstrual cycle irregularities, PMS, PMDD, and symptoms of menopause. More so, *Vitex agnus castus* have found usefulness for treating "lumpy" (fibrocystic) breasts, female infertility, preventing miscarriage in women with low levels of progesterone, controlling bleeding and placenta expulsion after childbirth, and increasing breast milk. Other notable use of *Vitex agnus castus* includes the treatment of lowered sexual vitality, with mental depression and loss of nervous energy (Vermeulen 2001). According to Katz (1995), *Vitex agnus castus* has proven to be effective with respect to

all psychic and somatic symptoms of the heterogeneous and multifaceted PMS. He alleged that that homoeopathy was listed among some of the therapies that could be used to treat hormonal disorders and premenstrual symptoms without the potential of unwanted effects of hormonal treatment.

A review by Stevenson and Ernst (2001) of complementary/ alternative therapies for PMS found that the herbal medicine *Vitex agnus castus* showed dramatic improvements during the first cycle of treatment and that there was stability during the remaining two cycles of the study. Berger *et al.* (2000) conducted a multicentre trial on *Vitex agnus castus* L extract Ze 400 in patients with PMS. Their study investigated the condition of PMS among 50 patients. According to their report, 43 patients completed the study protocol, which included eight menstrual cycles. More so, out of the 43 patients who completed the study, some were on concomitant oral contraceptives medication, while the rest were given one tablet (20 mg native extract) during three menstrual cycles. The main effect parameter was measured by means of the Moos Menstrual Distress Questionnaire (MMDQ). A Visual Analogue Scale (VAS) was use as a secondary parameter. Results showed that 38 patients judged the efficacy of treatment (improvement in symptoms) to be moderate to excellent. Only five patients indicated no efficacy. The researchers concluded that patients with PMS can be treated successfully with *Vitex agnus-castus* extract Ze 440.

Jang *et al.* (2014) conducted a systemic literature search using electronic databases on studies between 2002 and 2012. The study included randomised clinical trials of acupuncture and herbal medicines for PMS /PMDD. The search included 8 studies on different acupuncture techniques and 11 on herbal medicine, herbal medicines studies included *Vitex agnus castus* ,*hypericum* , Xioa yao san,*Ginko biloba* L,*Elsholtzia splendens*,*Cirsium japonicum* were identified. The herbal intervention showed better improvement (50% reduction of symptoms) over control groups except *Cirsium japonicum*. They concluded that there was limited evidence that supported the efficacy of alternative medicine interventions in controlling PMS/PMDD. There was no serious adverse report providing safety of the interventions.

Furthermore, the early report by Schellenberg (2001) also evaluated the efficacy of *Vitex agnus castus* L extract Ze 440. This was a randomised double-blinded study involving 170 women with PMS. The average age of participants was 36 years. Participants were given *Vitex agnus castus* tablets – one tablet daily or the matching placebo for a period of three months. Results showed an improvement of PMS symptoms in the active group compared to the non-active group. He concluded that *Vitex agnus castus* showed a positive effect and is tolerable in the treatment of PMS syndrome. Thus, it is likely that *Vitex agnus castus* will be effective to treat PMDD as well.

#### 2.10.2.3 *Melissa officinalis*

*Melissa officinalis* is effective for stress, anxiety, insomnia, indigestion, colic and depression management. It enhances memory and has calming effects (Maguire and Mody 2012). According to the European Medicines Agency (2011), there is a long traditional medicinal use of *Melissa officinalis* in Europe in the form of herbal tea, powdered herbal substance or aqueous/ethanolic extracts, for the relief of mild symptoms of mental stress, to aid sleep and for the symptomatic relief of mild gastrointestinal complaints including bloating and flatulence.

Cases *et al.* (2011) support this notion based on a pilot trial of *Melissa officinalis* leaf extraction. Their study involved the treatment of volunteers suffering from mild to moderate anxiety disorders and sleep disturbances using clinicians rating criteria. The primary outcomes showed improvement of symptoms, reducing anxiety manifestations by 18% and insomnia by 42%.

#### 2.10.2.4 *Valeriana officinalis*

*Valeriana officinalis* is most commonly used for sleep disorders, for conditions connected to anxiety and psychological stress including nervous asthma, hysterical states, excitability, fear of illness (hypochondria), headaches, migraine, and stomach upset. It is also recommended for over sensitiveness and nervous affections with changeable disposition (Vermeulen 2001). Furthermore, Kennedy *et al.* (2008) conducted a study on

the anxiolytic effects of a combination of *Melissa officinalis* and *Valeriana officinalis* on laboratory-induced stress. The study showed that a 600mg dose of the combination ameliorated the negative effects of the Defined Intensity Stressor Simulation (DISS) battery on ratings of anxiety. However, the highest dose (1800mg) showed an increase in anxiety that was less marked, but which reached significance during one testing session. All three doses led to decrements in performance on the Stroop task module within the battery, and the two lower doses led to decrements on the overall score generated on the DISS battery. The researchers concluded that these results suggest that a combination of *Melissa officinalis* and *Valeriana officinalis* possesses anxiolytic properties that deserve further investigation.

### **2.10.3** Placebo effect

Placebo is a substance with no active biological properties. In a controlled clinical trial, placebo 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).

There are a number of factors that contribute to the placebo effect. These include (1) the nature of the intervention (injections vs. pills), the use of hi-tech approaches (ultrasound), the colour of the medication or the unusual nature of the therapeutic encounter (homoeopathic consultation). (2) The nature of the therapist e.g. confidence, demeanour, empathy, warmth, reputation and prestige. (3) The time factor involved - the longer the consultation the better the placebo effect. (4) The patient, their trust in the therapist and their worldviews. (5) The nature of the complaint. (6) The therapeutic setting (Peters, 2001). The placebo effect dates back to Hippocrates who observed that certain gravely ill people seemed to recover through sheer "contentment". As reported by Grady (2004), placebo accounts for much of the benefit from anti-depressants and all the benefit from antibiotics taken for viral infections, which out any known therapeutic effects.

Hawkins (2001) highlights some of the placebo effects. This includes (1) the use of saline injection for acute pain, (2) the placebo component of anti-depressants being nearly twice as powerful as the pharmacological component, (3) and the 2.5 times greater death rate over a year follow up for post-myocardial infarction patients who took their prescribed

placebo medicine irregularly as compared to those who took it regularly. According to Benson and Friedman (1996), 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.

As PMDD is clinically unique from major depressive disorder and may have more complex features like irritability and anxiety-like features. Hence, a potential avenue of research should focus on the unique biological aspects of PMDD and PMS. Premenstrual disorders and their negative impact on a woman's quality of life has been an ongoing concern for both the patient and the physician. This could be attributed to the fact that they are often misdiagnosed or unrecognized. This means PMDD is currently under-recognized and under-treated, but it anticipated that this would change with the ever-increasing awareness of menstrual disorders.

The Centre for Women's Health (Massachusetts General Hospital 2015) reiterates the assessment that PMDD – especially with respect to adverse mood changes – affects social and interpersonal interactions that hamper the livelihood of the woman affected. Premenstrual dysphoric disorder can have economic costs. Chawla *et al.* (2002) conducted a study to quantify the economic burden of PMDD by assessing health care service use and related expenditures, work loss, role limitation, and productivity. Pharmaceutical treatments available for PMDD appear not to be maintaining long-term resolution of symptoms, with mainstream treatment being aim largely at the biological level of symptom management. Whilst these mood-altering substances have no doubt saved lives or brought transient relief to some patients, they do not seem to provide long-term benefits. Homoeopathic treatment on the other hand recognizes the complexity and individuality of the patient suffering from PMDD so it is suitable for treatment of PMDD.

## **CHAPTER THREE: RESEARCH METHODOLOGY**

### **3.1 RESEARCH DESIGN**

A quantitative research approach was adopted in this study. According to Johnson and Christensen (2008), a quantitative tests hypothesis with empirical data to see if they are supported.

#### **3.1.1 Study design**

This was a randomised double-blind placebo-controlled pilot study.

#### **3.1.2 Population**

A sample size of 30 consenting female participants between the ages of 18 and 35 years who met the Inclusion criteria according to the DSM-V (American Psychiatric Association 2013) were included in the study. They were randomly selected according to a randomisation sheet, with 17 assigned to the experimental group and 13 in the placebo group.

#### **3.1.3 Duration of each participant in the study**

The duration of the treatment protocol for each participant was three months from the first consultation to the final consultation. The measurement tools were applied in three consultations.

#### **3.1.4 Recruitment**

Participants were recruited through advertisements (Appendix J) that were placed on noticeboards at DUT, other institutions, health shops, shopping malls, local public clinics, hospitals, libraries and via word of mouth.

#### **3.1.5 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.



### **3.1.6 Sampling process**

Randomisation was accomplished by an independent, qualified and registered homoeopath within the Department of Homoeopathy and nominated by the Department of Homoeopathy Research Committee (DRC). A randomisation table of 1-30 was designed by the researcher and submitted to the above mentioned independent person by the supervisor who was not blinded. The independent person performed randomisation by assigning the random numbers from random number tables (1-30) to the two groups, which are treatment or placebo. The outcome resulted in 17 participants in the experimental group and 13 participants in the control group.

### **3.1.7 Inclusion and exclusion criteria**

#### *3.1.7.1 Inclusion criteria*

Participants who met the inclusion criteria for PMDD as stated in DSM-V (American Psychiatric Association 2013) (Appendix F) were accepted as part of the study.

#### *3.1.7.2 Exclusion criteria*

A. 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).

B. 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).

C. Other exclusion criteria:

Participants who did not meet the inclusion criteria for PMDD as stated by DSM-V (American Psychiatric Association 2013).

Participants who were older or younger than the age category of the study (18-35 years).

Participants who did not reside in or around Durban, KwaZulu-Natal.

Participants who were currently on any treatment for PMDD.

Participants who had a co-existing chronic medical or mental condition.

Participants intending to conceive in the course of the study.

Participants who had surgery in the past six weeks.

Participants on any recreational drugs.

Participants currently on contraceptives.

Participants who did not have regular periods.

Pregnant participants were excluded from the study.

This criterion ensured the exclusion of individuals who could have contributed extraneous factors which may have impacted the study.

### **3.2 Ethical considerations and confidentiality**

Permission for this study was granted by the Institutional Research Ethics Committee (IREC) of the Faculty of Health Sciences, DUT (Appendix A). Letters of permission were sent to the Clinic Director, Homoeopathy Head of Department, and permission was granted by all relevant stakeholders (Appendixes Ga to Ge). Information Letters were given to all potential participants and only consenting patients were included in the study after signing the consent form (Appendixes E (a) and E (b)).

Prior to commencement of the study, letters requesting the use of the Homoeopathic Day Clinic and dispensary were sent to the relevant individuals (Appendix F). Permission to use a DUT facility, students and staff was requested from the Research and Postgraduate Support Director, Professor Sibusiso Moyo (Appendix G(c)). Once permission was granted, the study commenced.

### **3.3 Manufacturing process of the remedy**

The complex was prepared by Homoeopathic Fusion according to the German Homoeopathic Pharmacopoeia (GHP) (Method 10) (Appendix K).

### **3.4 Data collection process**

#### **3.4.1 The Procedure**

The procedure was divided into three consultations that took place over a span of 12 weeks.

### 3.4.2 Consultation details

There were three consultations in which the measurement tools were applied. Pregnancy tests were conducted at all three consultations. The first consultation was regarded as a baseline. Thereafter the participants were seen for the second and third consultations which were after each cycle of menses (within 1 week after each period/menses). The participants were given treatment according to the randomisation list

#### 3.4.2.1 Consultation one: (at the onset/start of menstruation)

- Step One: Participants were fully informed about the study. The participants were given the information letter (Appendix D). Participants had an opportunity to ask questions about the study.
- Step Two: Participants signed the consent form (Appendix E) upon agreeing to participate in the study.
- Step Three: On both the information letter and consent form there was information regarding participants not being forced to participate in the study and that there was no remuneration for taking part in the study. Participants were told that they could withdraw at any time during the study without any prejudice and lastly that there were samples of bodily fluid required specifically for the research, urine sample for the purpose of pregnancy testing in order to exclude pregnant participants in the interest of the participants).
- Step Four: The researcher applied the measurement tools (Appendixes B and C) once participants met inclusion criteria (Appendix F) and had signed the consent form (Appendix E).
- Step Five: A detailed case history was taken (Appendix L).
- Step Six: A full physical examination was performed and a SOAPE note was completed by the researcher (Appendix M).
- Step Seven: Participants proceeded to the Clinic reception area where the dispenser on duty dispensed the allocated treatment in a bottle which was fully labelled with instructions on when and how to take it (Appendix N).

- Step Eight: Treatment was dispensed according to the randomisation list drawn by an independent person.

#### *3.4.2.2 Consultation two*

- Step Nine: The researcher called the participants to remind them of their next consultation, within 1 week after the next period/menses.
- Step Ten: The researcher applied the measurement tools (Appendix B and C) and took a urine sample for the purpose of pregnancy testing in order to exclude pregnant participants in the interest of the participants.
- Step Eleven: A detailed follow up case was taken (Appendix O).
- Step Twelve: A repeat of steps six to step eight from consultation one.

#### *3.4.2.2 Consultation three*

- Step Thirteen: The researcher called the participants to remind them of their next consultation, within 1 week of their next period/menses.
- Step Fourteen: The researcher applied the measurement tools (Appendix B and C) and took a urine sample for the purpose of pregnancy testing in order to exclude pregnant participants in the interest of the participants.
- Step Fifteen: A detailed follow up case was taken (Appendix O).
- No medication was prescribed on this final follow up.
- The participants were thanked for their participation in the study and were informed that they would be welcomed for further treatment at the Homoeopathic Day Clinic should they need it. Those in the placebo group were informed they would get free treatment at the end of the research study.

### **3.5 Posology and dosage**

1. Treatment was dispensed in a 50ml amber screw top bottle.
2. Participants were required to take the treatment at least ½ hour before a meal OR ½ an hour after a meal.
3. Participants were required to take the treatment from the 3<sup>rd</sup> or 4<sup>th</sup> day into the bleed/menses through the entire cycle period.
4. Participants were told to open the bottle and take medication as instructed on the label.

5. The dosage used was 20 drops in a little water twice daily.
6. Participants were told to avoid eating mint, or using camphor (e.g. Vicks) while on treatment.
7. Participants were told to store the treatment away from heat, light and electromagnetic radiation (e.g. T.V., computers and cellphones).
8. Participants were told that if they would be drinking coffee, they would have to wait ½ hour after taking the treatment, before having any.

### **3.6 Placebo**

In clinical trials a placebo is commonly used. According to the Oxford English Dictionary (2017) a placebo is an inert or innocuous substance used especially 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 a therapeutic effect. Therefore, during a clinical study, active medication is tested against a control receiving a placebo to make sure that any positive results takes 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 Geddes 2006).

In this clinical study an active oral homoeopathic mother tincture complex treatment comprising (*Vitex agnus castus*, *Melissa officinalis* and *Valeriana officinalis*) was tested against inactive oral drops with 30% ethanol mixed with distilled water which was the same in colour and taste but with no active ingredient. The placebo group received medication at the end of the study.

### **3.7 Data analysis**

All data captured and information gathered was analysed using SPSS 24.0. Inferential and non-parametric analysis of data was performed using repeated measures ANOVA, pie charts, bar graphs, and tables to present results. A p-value of 0.05 was considered statistically significant. Nominal and ordinal data from the Psychological Distress Scale and Visual Analogue Scale questionnaires were reported as frequencies. Pie charts, bar graphs and tables were used to present the results and non-parametric and inferential

analysis of data was performed using the Greenhouse-Geisser correction tool as appropriate.

The study was guided by the research problem. Data was collected, organised, and interpreted to give meaning to the data which led to a resolution of the problem, thus testing the hypotheses and providing an answer to a question. The aim of the research was to determine the effectiveness of a homoeopathic mother tincture complex in the treatment of PMDD. In the next chapter the results are presented using tables, bar charts and pie charts.

## CHAPTER FOUR: PRESENTATION OF RESULTS

This chapter presents the outcome of the data gathering process and reports on the results accordingly. In this section, the Kessler psychological distress scale and visual analogue scale were the primary tools that were used to collect data. This was distributed to 30 participants visiting the Homeopathic clinic. The participants were separated into two groups: group 1 was the Experimental group and group 2 was the Control group. The data collected from the responses was analysed with SPSS (version 24<sup>®</sup>) in relation to the two objectives outlined in Chapter One, that is: (1) To determine the efficacy of a homoeopathic mother tincture complex (*Vitex agnus castus*, *Melissa officinalis* and *Valeriana officinalis*) (compared to a placebo) in the management of Premenstrual Dysphoric Disorder in terms of the single item Visual Analogue Scale, (2) To determine the efficacy of a homoeopathic mother tincture complex (*Vitex agnus castus*, *Melissa officinalis* and *Valeriana officinalis*) (compared to a placebo) in the management of PMDD in terms of the Kessler Psychological Distress Scale.

All the data in the sections below were statistically analysed in an attempt to evaluate the if mother tincture complex (*Vitex agnus castus*, *Melissa officinalis* and *Valeriana officinalis*) was effective in the management of PMDD using both the Visual Analogue and Kessler Psychological Distress scale.

### 4.1.1 Data parameter

Group 1 = Experimental/ Treatment/ complex group

Group 2 = Placebo/ control group

*p*-value: observed significance level (*p* value 0.05).

### 4. 1.2 Criteria for the admissibility of the data

1. The only data that was accepted for statistical analysis chapter was that obtained from this research study.
2. The only data used in the analysis was collected in the manner described in Chapter Three.

3. Only data for participants who completed the research study was collected.
4. No data was excluded from statistical analysis.

#### 4.1.3. Treatment group split

Table 4.1 indicates the number of participant per each of the sample group. As seen below, 56.7% of the participants were in the experimental group, while 43.3% were in the control group.

**Table4. 1 Treatment group**

Treatment group	Frequency	Percent
Control	13	43.3
Experimental	17	56.7
Total	30	100.0

#### 4.2 Demographic information of the participants

This section summarises the demographic information of the participants. It was observed that the participants had an average mean age of  $23.93 \pm 4.008$ , with a minimum age of 18years and a maximum age of 32. This suggests that the treatment group consists of participants in their early 20s. The racial profile Results showed that participants were mostly Black (97%), while non-Black make up the remaining percentage (3%). The educational qualification profile of participants showed that (63.3%) were participants with a matric qualification, while the participant with a master degree (3.3%) constitute the lowest proportion of the participants. The language profile showed that (90%) of the participant's speak IsiZulu while an equal (3.3%) representation spoke Xhosa, SiSwati, and English, respectively. The marital profile showed that 96.6% of the participant were single with 3.3% married and the Occupation profile showed that 48.3% of the singles are scholars, 34.5% workers, and 17.2% unemployed. Of interest, all the married participants indicated to be workers (100%).



**Table4. 2 Demographic information of participants**

demographics	Mean standard deviation/ Frequency
Mean Age	23.93
Race	
Blacks	97%
whites	3%
Marital status	
Single	96.6%
married	3.3%
Educational qualification	
Matric	63.3%
Diploma	6.7%
B Tech	10%
degree	16.7%
Masters	3.3%
Home languages	
English	3.3%
IsiZulu	90%
Isiswati	3.3%
Xhosa	3.3%
Occupation	
Students	48.3%
Unemployed	34.5%
workers	17.2%

### 4.3 The effect of time and treatment on the Kessler psychological distress scale

A mixed ANOVA was used to test the effect of time and treatment on the Kessler distress measure. Time is the within-subject factor and is a repeated measure. The between-subject factor is group (control and experimental). The measured dependent variable is the KPD distress score.

#### 4.3.1 Descriptive Statistics for the distressed measurement on KPD

Results showed the average distressed measured at a three time points. It can be gathered the mean value at different time point was different for both the control and experimental group. For the control group for example, K10A had the highest mean value ( $29.31 \pm 4.94$ ) while the lowest mean value was measured for K10C ( $18.23 \pm 5.20$ ). Similarly, for the experimental group, the highest distress measured was recorded for K10A ( $28.76 \pm 7.45$ ) and the lowest for K10C ( $16.35 \pm 6.89$ ). This suggests that the participant were more likely distressed at K10A than any other time period. Overall, the highest distressed measure was recorded for the control group at K10A while the lowest distressed measured was observed for the experimental group at K10C.

**Table4. 3 Descriptive statistics of the measure of average distress measure at three time points for the two groups (KPD)**

Treatment Group		Mean	Std. Deviation	N
K10A	Control	29.31	4.939	13
	Experimental	28.76	7.479	17
	Total	29.00	6.406	30
K10B	Control	21.31	5.907	13
	Experimental	19.29	8.099	17
	Total	20.17	7.188	30
K10C	Control	18.23	5.199	13
	Experimental	16.35	6.891	17
	Total	17.17	6.187	30

Note:

K10A represents first consultation measured with KPD

K10B represents second consultation measured with KPD

K10C represents third consultation measured with KPD

### 4.3.2 ANOVA tests of within-subjects and between effects for the distressed measured with KPD.

As shown in Table 4.4, the average score differs significantly between time points beyond the 0.01 interval level:  $F(2,56) = 37.345$ ;  $p < 0.005$ . Partial eta squared = 0.572 representing a large effect. This suggests that time of treatment had as significant differences in both the control and experimental group and the differences between the three time measured was large. To gain further insight to the level of differences per treatment time, Post-hoc tests was done. As given in Table 4.4.1, and table 4.4.2 the Post-hoc test, using the Bonferroni correction, revealed that distress at time K10A ( $29.036 \pm 1.200$ ) is significantly higher than at times K10B ( $20.301 \pm 1.334$ ) and K10C ( $17.292 \pm 1.146$ ),  $p < .0005$  in each case. Distress at time K10B was significantly higher than at time K10C ( $p < 0.05$ ).

**Table4. 4 Tests of within-subjects effects (KPD)**

Source		Type III Sum of Squares	Df	Mean Square	F	Sig.	Partial Eta Squared
Time	Sphericity Assumed	2193.198	2	1096.599	37.345	.000	.572
time * group	Sphericity Assumed	9.731	2	4.866	.166	.848	.006
Error(time)	Sphericity Assumed	1644.380	56	29.364			

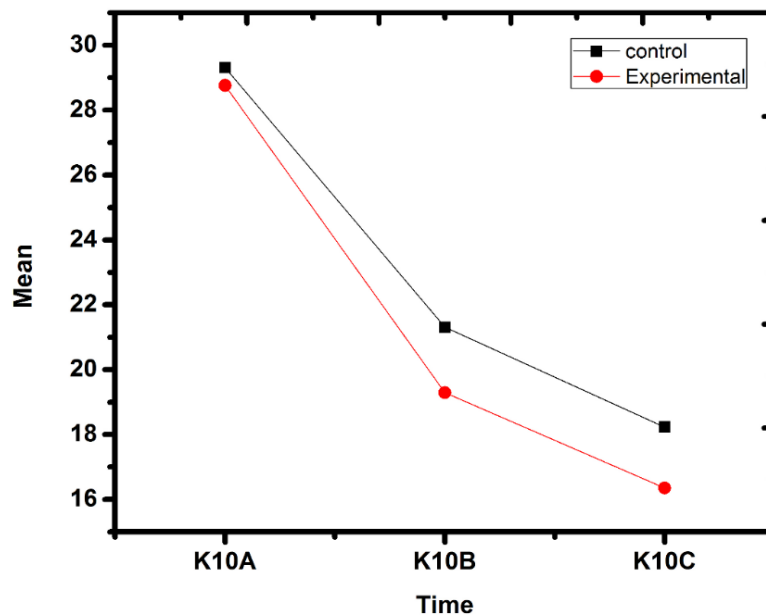
**Table4. 4.1 Estimates, measure:distress (KPD)**

Time	Mean	Std. Error	95% Confidence Interval	
			Lower-Bound	Upper-Bound
K10A	29.036	1.200	26.578	31.494
K10B	20.301	1.334	17.568	23.034
K10C	17.292	1.146	14.944	19.640

**Table4.4.2 Pairwise comparisons, measure:distress (KPD)**

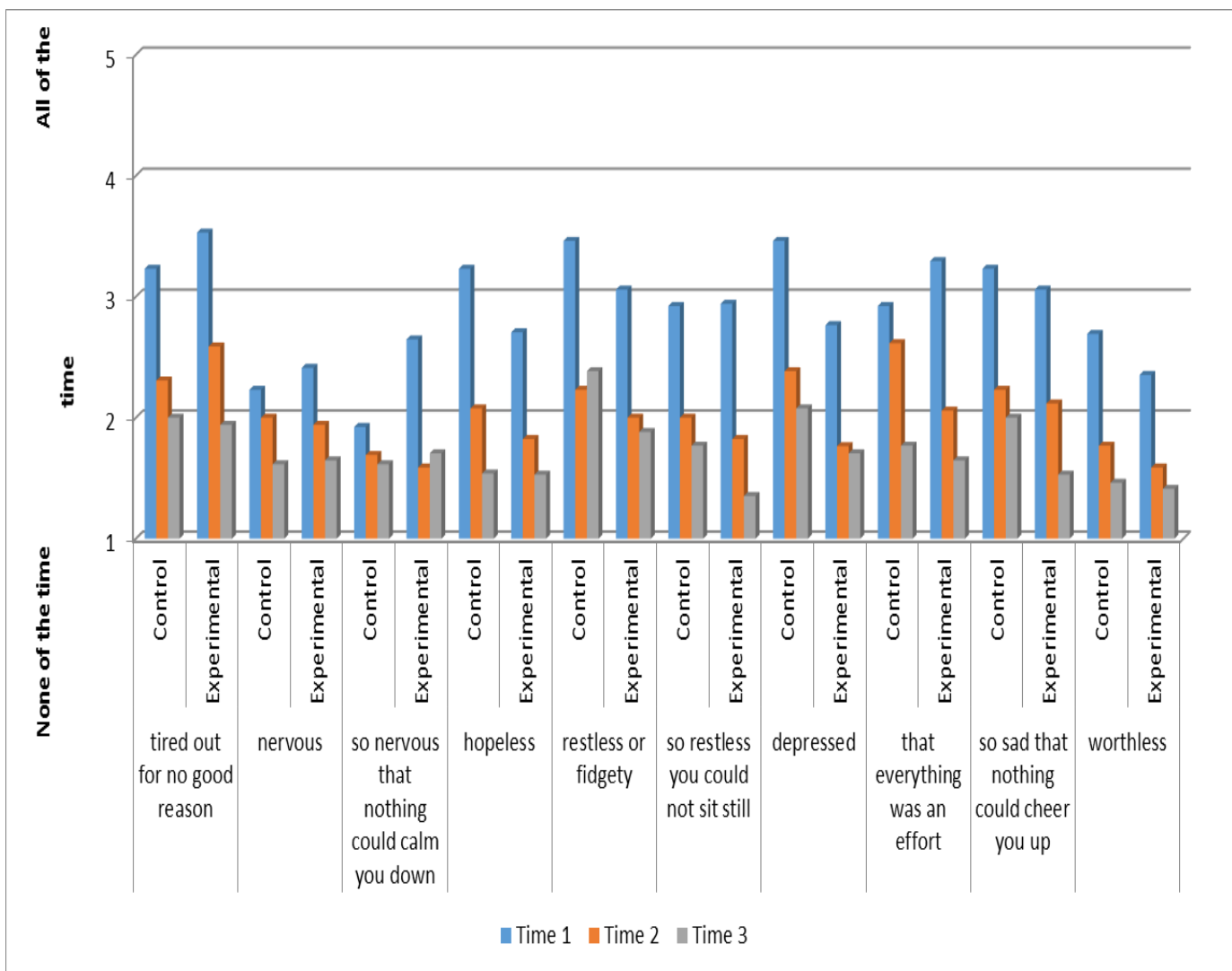
(I) time	(J) time	Mean Difference (I-J)	Std. Error	Sig. <sup>a</sup>	95% Confidence Interval for Difference <sup>a</sup>	
					Lower-Bound	Upper-Bound
K10A	K10B	8.735*	1.381	.000	5.218	12.253
	K10C	11.744*	1.662	.000	7.512	15.977
K10B	K10A	-8.735*	1.381	.000	-12.253	-5.218
	K10C	3.009*	1.144	.041	.096	5.922
K10C	K10A	-11.744*	1.662	.000	-15.977	-7.512
	K10B	-3.009*	1.144	.041	-5.922	-.096
Based on estimated marginal means						
*. The mean difference is significant at the .05 level.						
a. Adjustment for multiple comparisons: Bonferroni.						

Figure 4.1 below shows the estimated marginal means of distress between the two groups (control and experiment) across three different time periods. Time period 1 denotes Consultation K10A, time period 2 depicts Consultation K10B and time period 3 denotes Consultation K10C. At a glance, a similar distressed pattern is observed between the two groups. For example, as the treatment progressed, it was noticed that the distressed pattern measured reduces. Overall, the experimental group were less distressed at the end of the third (K10C) consultation.



**Figure 4. 1: Estimated marginal means of distress (KPD)**

Figure 4.2 below illustrates the difference in the results for the two groups before and after treatment. A consistent reduction in the distressed symptom is observed, this strongly suggests the effectiveness of the treatment in distressed management. More so, and apart from the condition “so nervous that nothing could calm you down”, in all instance, the experimental group showed less distressed condition measured with Kessler psychological distress scale after the third consultation.



**Figure 4. 2: The difference in the results for the two groups before and after treatment (KPD)**

#### 4.4 The effect of time and treatment of the recorded symptoms over time on the visual analogue scale

As explained in section 4.3, mixed factorial ANOVA was applied to test the hypothesis outlined in Chapter One, Section 1.4.1. The repeated measures was used to test for significant differences across time and treatment between the two groups (control and experimental).

##### 4.4.1 Descriptive Statistics for the distressed measurement on Visual Analogue Scale

This section summarizes the descriptive distressed parameter measured on the VAS at a different time of treatment. It was observed that the mean value at different time point was different for both the control and experimental group. For the control group for example, AVASTOT had the highest mean value ( $36.92 \pm 8.91$ ) while the lowest mean value was measured for CVAOTOT ( $24.15 \pm 9.95$ ). Similar trend was also observed for the experimental group. As gleaned below, the highest distress measured was recorded for AVASTOT ( $39.35 \pm 6.33$ ) and the lowest for CVAOTOT ( $20.71 \pm 11.24$ ). This suggests that the participant were more likely distressed at AVASTOT than any other time. Overall, the highest distressed measure was recorded for the experimental group at AVASTOT while the lowest distressed measured was also observed for the experimental group at CVAOTOT.

**Table4. 5 Descriptive statistics (VAS)**

group		Mean	Std. Deviation	N
AVASTOT	Control	36.92	8.911	13
	Experimental	39.35	6.334	17
	Total	38.30	7.516	30
BVAOTOT	Control	28.92	5.838	13
	Experimental	27.88	10.559	17
	Total	28.33	8.711	30
CVAOTOT	Control	24.15	9.949	13
	Experimental	20.71	11.240	17
	Total	22.20	10.662	30

Note:

AVASTOT represents first consultation measured with VAS

BVAOTOT represents second consultation measured with VAS

CVAOTOT represents third consultation measured with VAS

#### 4.4.2: ANOVA tests of within-subjects and between effects for the distressed measured with VAS

The average score differs significantly between time points beyond the 0.01 interval level:  $F(2, 56) = 37.526$ ;  $p < 0.005$ . Partial eta squared = 0.573 representing a large effect. This suggests that time of treatment had as significant differences in both the control and experimental group and the differences between the three time measured was large. Moreover, it can be gathered that there was no significant interaction between time and treatment ( $F(2, 56) = 1.303$ ;  $p > 0.05$ ). Partial eta squared = 0.044 representing a small effect. This indicates that the pattern of distressed measured in the control with time was the same with that measured in the experimental group.

The mean estimate for the treatment as well as Post-hoc tests, using Bonferroni correction. It was observed that distress at time AVASTOT ( $38.138 \pm 1.390$ ) is significantly higher than at times BVAOTOT ( $28.403 \pm 1.630$ ) and CVAOTOT ( $22.430 \pm 1.972$ ),  $p < .0005$  in each case. Distress at time BVAOTOT is significantly higher than at time CVAOTOT ( $p < 0.01$ ).

**Table4. 6 Estimates, measure: distress (VAS)**

Time	Mean	Std. Error
AVASTOT	38.138	1.390
BVASTOT	28.403	1.630
CVASTOT	22.430	1.972

**Table4. 7 Pairwise comparisons, measure: measure1 (VAS)**

(I) time	(J) time	Mean Difference (I-J)	Std. Error	Sig. <sup>a</sup>	95% Confidence Interval for Difference <sup>a</sup>	
					Lower-Bound	Upper-Bound
AVAS TOT	2	9.735*	1.722	.000	5.351	14.120
	3	15.708*	2.206	.000	10.090	21.326
BVAS TOT	1	-9.735*	1.722	.000	-14.120	-5.351
	3	5.973*	1.490	.001	2.180	9.766
CVAS TOT	1	-15.708*	2.206	.000	-21.326	-10.090
	2	-5.973*	1.490	.001	-9.766	-2.180
Based on estimated marginal means						

Figure 4.3 below shows the estimated marginal means of distress between the two groups (control and experiment) across three different time periods. Time period 1 denotes Consultation AVASTOT, time 2 depicts Consultation BVAOT and time 3 denotes Consultation CVAOT. Similar distressed trend could be observed for both the control and treatment group. For example, at the treatment progress, it was noticed that the distressed pattern measured reduces, that is Time 1 > time 2 > time 3. Overall, the experimental group were less distressed at the end of the CVAOT (time 3) consultation.

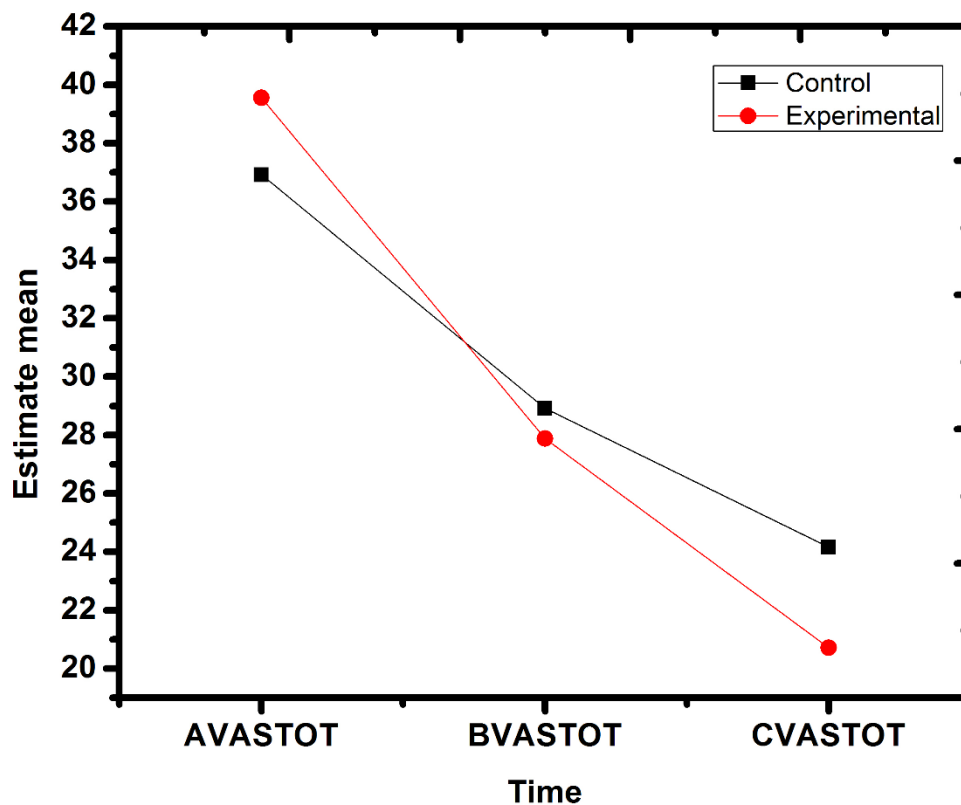


Figure 4. 3: Estimated marginal means of measure 1 (VAS)



#### 4.4.3: Effect of treatment of recorded symptoms with VAS

The previous section had compared between the two treatment group, the effect of distressed measured with VAS. This section summarizes individual distressed symptom's using the VAS.

Table 4.8 below depicts the effect of treatment of recorded symptoms over time on the VAS. Time periods 1-3 (used to record the mean and standard deviation of symptoms over 3 consultation periods during the study) represent Consultations 1-3. The measurement of time and treatment using the VAS was conducted using 2 groups: Control and Experiment. A consistent reduction in the distressed symptom is observed for the treatment group as the treatment progress from 1-3. Equally important, and apart from the symptoms "normal lifestyle", the mean treatment for the experimental group showed lower mean symptoms when compared against the control at the end of consultation time 3. This suggests that the experimental treatment was more effective in the management of the presented symptoms.

**Table4. 8 The effect of treatment of recorded symptoms over time (VAS)**

Symptoms	Group	Time measure according to Consultations 1 – 3						N
		Mean			Standard Deviation			
		1	2	3	1	2	3	
Before you start your menses, how do you feel?	Control	6,38	4,69	4,23	2,103	1,974	2,488	13
	Experiment	6,53	5	3,82	2,787	2,806	2,506	17
Depression & Irritability	Control	7,08	5,31	4,38	1,656	1,316	1,895	13
	Experiment	7,12	5	3,71	1,799	2,179	2,616	17
Anxiety	Control	5,62	4,38	3,46	1,805	1,805	2,066	13
	Experiment	5,82	4,41	3	2,298	2,21	2,062	17
Energy Levels	Control	5,62	4,85	4,54	2,755	2,267	2,74	13
	Experiment	7,06	5,18	3,53	2,436	2,298	1,807	17
Sleeping pattern	Control	5,54	4,77	4,31	2,787	2,242	2,926	13
	Experiment	6,53	4,24	3,35	2,741	2,359	2,344	17
Normal Lifestyle	Control	6,69	4,92	3,23	2,25	1,656	1,922	13
	Experiment	6,29	4,06	3,29	2,756	2,358	2,285	17

#### 4.4.4: Mixed ANOVA comparison on the effect of treatment of recorded symptoms with VAS

In order to draw parallel comparison on the effectiveness of the treatment in the management of the distressed symptoms presented, mixed factorial ANOVA with Greenhouse-Geisser (G-G) adjustment was used to compare the level of significant differences among the participant responses for the three time of consultation. The null hypothesis claims that there is no differences in their responses. The alternate states that there is a significant difference in how the participants had responded in treatment of the symptoms presented. The results are shown in Table 4.9 below. The significant values (p-values) are less than 0.05 (the level of significance), it implies that the management of the symptoms differ across the three consultation periods, overall.

**Table4. 9 Tests of within-subject effects using the Greenhouse-Geisser (G-G) correction tool – combined for all six-symptom measures (VAS)**

Symptoms	Type III Sum of Squares	df	Mean Square	F	Significance
Before you start your menses, how do you feel?	90.069	1.782	50.536	19.503	.000
Depression & Irritability	140.665	1.574	89.348	28.038	.000
Anxiety	91.368	1.541	59.289	34.630	.000
Energy Levels	78.750	1.610	48.918	11.527	.000
Sleeping pattern	75.174	1.523	49.365	10.746	.001
Normal Lifestyle	156.725	1.478	106.031	27.065	.000

Drawing from above, it is sufficient to say that the management of distressed symptoms differs across the various time of consultation. To gain further insight to the pattern of

differences, each of the six items outlined in Table 4.14 was analysed separately. The results are summarized in the sections below.

#### 4.4.5 Mauchly's Test of Sphericity

The test for sphericity for the participants rating of the six items are presented. The Mauchly test has a p-value of 0.014, which suggests evidence of heterogeneity of covariance of the responses. As a general rule, lower Huynh-Feldt are used with smaller departures from sphericity, while Greenhouse-Geisser are used when the departures are large. The Greenhouse-Geisser adjustment of the ANOVA (F) test was therefore used in assessing the distressed measure on VAS.

##### 4.4.5.1 Descriptive statistics for Item 1: How you feel before menses start

As shown in Table 4.10, it is observed that time 1 (A) had the highest mean symptom while time 3 (C) had the lowest mean symptoms. At the end of consultation time 3 (C), it can be gathered that the mean value ( $3.82 \pm 2.51$ ) for the experimental group was lower than the control ( $4.23 \pm 2.49$ ). This suggests that the experimental treatment was more effective in the management of menses when compared against the control.

**Table 4. 10 Descriptive statistics, Item 1 (VAS)**

	Group	Mean	Std. Deviation	N
A How you feel before menses start	Control	6.38	2.103	13
	Experimental	6.53	2.787	17
	Total	6.47	2.474	30
B How you feel before menses start	Control	4.69	1.974	13
	Experimental	5.00	2.806	17
	Total	4.87	2.446	30
C How you feel before menses start	Control	4.23	2.488	13
	Experimental	3.82	2.506	17
	Total	4.00	2.464	30

#### 4.4.5.2. ANOVA assessment for Item 1: How you feel before menses start

The average score differs significantly between time points beyond the 0.01 interval level: ( $F(1.782, 49.903) = 19.503$ ;  $p < 0.005$ ) with Greenhouse-Geisser adjustment. Partial eta squared = 0.411 representing a large effect. This suggests that time of treatment had a significant differences in both the control and experimental group and the differences between the three time measured was large.

More so, and in respect to the treatment group per time, there was no significant interaction between time and treatment ( $F(1.782, 49.903) = 1.161$ ;  $p > 0.05$ ). Partial eta squared = 0.016 representing a small effect. This indicates that the pattern of distressed measured in the control with time was the same with that measured in the experimental group.

**Table4. 11 Tests of within-subjects effects, Item 1 (VAS)**

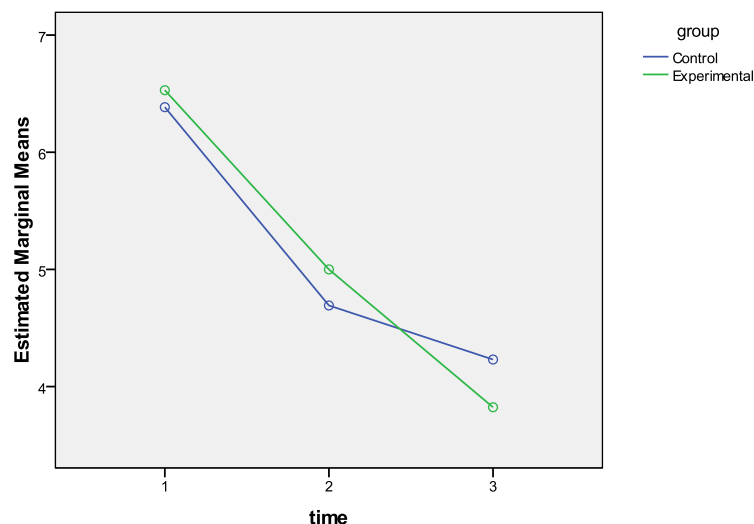
Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Time	Greenhouse-Geisser	90.069	1.782	50.536	19.503	.000	.411
time*group	Greenhouse-Geisser	2.069	1.782	1.161	.448	.619	.016
Error(time)	Greenhouse-Geisser	129.309	49.903	2.591			

Table 4.12 showed that time 1 in the management of menses was significantly higher than time 2 and time 3, respectively ( $p < 0.01$ ). No significant difference was observed for time 2 and 3 ( $p > 0.05$ ). This suggests that little changes occurred in the menses management for both the treatment group in consultation time 2 and 3.

**Table4. 12 Pairwise comparisons, Item 1 (VAS)**

(I) time	(J) time	Mean Difference (I-J)	Std. Error	Sig. <sup>a</sup>	95% Confidence Interval for Difference <sup>a</sup>	
					Lower-Bound	Upper-Bound
1	2	1.611*	.386	.001	.628	2.594
	3	2.430*	.456	.000	1.270	3.590
2	1	-1.611*	.386	.001	-2.594	-.628
	3	.819	.337	.065	-.039	1.677
3	1	-2.430*	.456	.000	-3.590	-1.270
	2	-.819	.337	.065	-1.677	.039
Based on estimated marginal means						
*. The mean difference is significant at the .05 level.						
a. Adjustment for multiple comparisons: Bonferroni.						

Figure 4.5 further illustrates the differences in the management of menses at the different times of consultation. At a glance, it can be observed that time scores change over time (time1 > time 2 and time 3). In addition, it can be gleaned that the pattern of change between the two groups differs. Overall, the experimental group had lower mean value at time 3 than the control. This indicates that the experimental treatment was more effective in the management of menses at the end of treatment when compared against the control.

**Figure 4. 5: Estimated marginal means of distress, Item 1 (VAS)**

#### 4.4.6 Descriptive statistics for Item 2: Depression and irritability

As shown in Table 4.13, it can be observed that time 1 (A) had the highest mean presented symptom while time 3 (C) had the lowest mean symptoms. At the end of consultation time 3 (C), it can be gathered that the mean value ( $3.71 \pm 2.62$ ) for the experimental group was lower than the control ( $4.38 \pm 1.89$ ). This suggests that the experimental treatment was more effective in the management of depression and irritability at the end of treatment when compared against the control.

**Table4. 13 Descriptive statistics, Item 2 (VAS)**

	group	Mean	Std. Deviation	N
A Depression and irritability	Control	7.08	1.656	13
	Experimental	7.12	1.799	17
	Total	7.10	1.709	30
B Depression and irritability	Control	5.31	1.316	13
	Experimental	5.00	2.179	17
	Total	5.13	1.833	30
C Depression and irritability	Control	4.38	1.895	13
	Experimental	3.71	2.616	17
	Total	4.00	2.319	30

##### 4.4.6.1. ANOVA assessment for Item 2: Depression and irritability

As shown in Table 4.14, the average score differs significantly between time points beyond the 0.01 interval level: ( $F(1.574, 44.081) = 28.038$ ;  $p < 0.001$ ) with Greenhouse-Geisser adjustment. Partial eta squared = 0.500 representing a large effect. This suggests that time of treatment had a significant differences in both the control and experimental group and the differences between the three time measured was large.

More so, and in respect to the treatment group per time, there was no significant interaction between time and treatment ( $F(1.574, 44.081) = 0.380$ ;  $p > 0.05$ ). Partial eta squared = 0.013 representing a small effect. This indicates that the pattern of distressed measured in the control with time was the same with that measured in the experimental group.

**Table4. 14 Measure: Tests of within-subjects effects, Item 2 (VAS)**

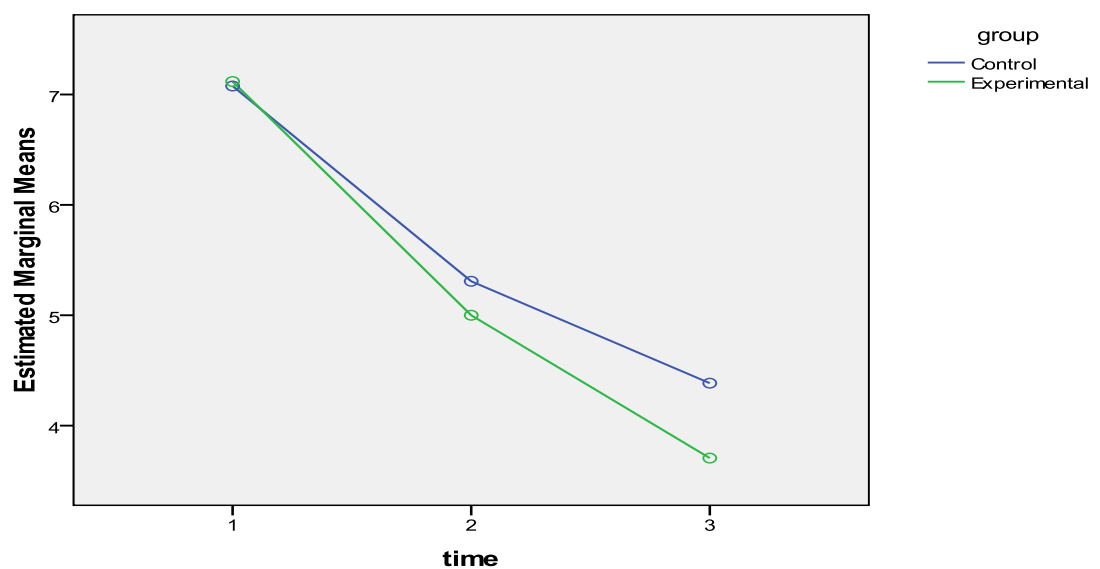
Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Time	Greenhouse-Geisser	140.663	1.574	89.348	28.038	.000	.500
time group *	Greenhouse-Geisser	1.907	1.574	1.211	.380	.636	.013
Error(time)	Greenhouse-Geisser	140.471	44.081	3.187			

Additionally, the pairwise comparison test shown in Table 4.15 revealed that time 1 in the management of depression and irritability was significantly higher than time 2 and time 3, respectively ( $p < 0.01$ ). Equally, significant difference was also observed for time 2 and 3 ( $p > 0.05$ ). This indicates that the management of depression and irritability differs across the three time of consultation.

**Table4. 15 Pairwise comparisons, Item 2 (VAS)**

(I) time	(J) time	Mean Difference (I-J)	Std. Error	Sig. <sup>a</sup>	95% Confidence Interval for Difference <sup>a</sup>	
					Lower-Bound	Upper-Bound
1	2	1.943*	.385	.000	.964	2.923
	3	3.052*	.506	.000	1.765	4.339
2	1	-1.943*	.385	.000	-2.923	-.964
	3	1.109*	.327	.006	.275	1.942
3	1	-3.052*	.506	.000	-4.339	-1.765
	2	-1.109*	.327	.006	-1.942	-.275
Based on estimated marginal means						
*. The mean difference is significant at the .05 level.						
a. Adjustment for multiple comparisons: Bonferroni.						

Figure 4.6 further illustrates the differences in the management of depression and irritability at the different time of consultation. At a glance, it can be observed that time scores change over time (time1 > time 2 and time 3). In addition, it can be gleaned that the pattern of change between the two groups differs. Overall, the experimental group had lower mean value at time 3 than the control. This indicates that the experimental treatment was more effective in the management of depression and irritability at the end of treatment when compared against the control.



**Figure 4. 6: Estimated marginal means of distress, Item 2 (VAS)**

#### **4.4.7 Descriptive statistics for Item 3: Anxiety**

As shown in Table 4.16, it can be observed that time 1 (A) had the highest mean presented symptom while time 3 (C) had the lowest mean symptoms. Overall, and at the end of consultation time 3 (C), it can be gathered that the mean value ( $3.00 \pm 2.06$ ) for the experimental group was lower than the control ( $3.46 \pm 2.07$ ). This suggests that the experimental treatment was more effective in the management of participant's anxiety at the end of treatment when compared against the control.



**Table4. 16 Descriptive statistics, Item 3 (VAS)**

	Group	Mean	Std. Deviation	N
A Anxiety	Control	5.62	1.805	13
	Experimental	5.82	2.298	17
	Total	5.73	2.067	30
B Anxiety	Control	4.38	1.805	13
	Experimental	4.41	2.210	17
	Total	4.40	2.010	30
C Anxiety	Control	3.46	2.066	13
	Experimental	3.00	2.062	17
	Total	3.20	2.041	30

#### 4.4.7.1 ANOVA assessment for Item 3: Anxiety

As shown in Table 4.17, the average score differs significantly between time points beyond the 0.01 interval level: ( $F(1.541, 43.150) = 34.630$ ;  $p < 0.001$ ) with Greenhouse-Geisser adjustment. Partial eta squared = 0.553 representing a large effect. This suggests that time of treatment had a significant differences in both the control and experimental group and the differences between the three time measured was large.

More so, and in respect to the treatment group per time, there was no significant interaction between time and treatment ( $F(1.541, 43.150) = 0.670$ ;  $p > 0.05$ ). Partial eta squared = 0.023 representing a small effect. This indicates that the pattern of distressed measured in the control with time was the same with that measured in the experimental group.

**Table4. 17 Tests of within-subjects effects, Item 3 (VAS)**

Source		Type III Sum of Squares	Df	Mean Square	F	Sig.	Partial Eta Squared
Time	Greenhouse-Geisser	91.368	1.541	59.289	34.630	.000	.553
time group *	Greenhouse-Geisser	1.768	1.541	1.147	.670	.479	.023
Error(time)	Greenhouse-Geisser	73.876	43.150	1.712			

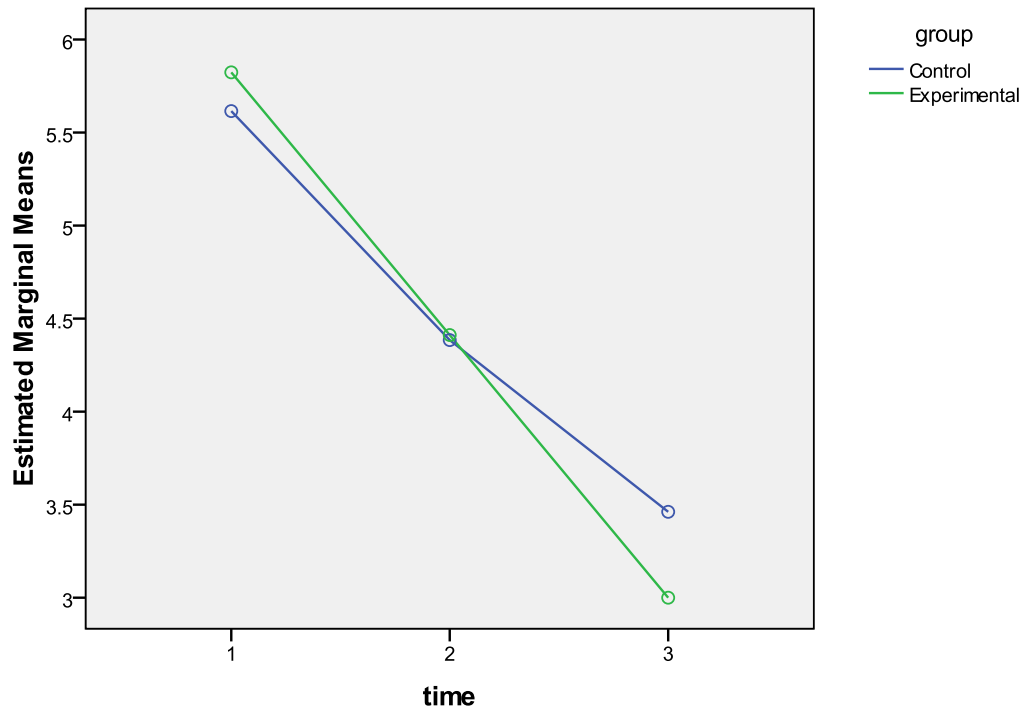
The pairwise comparison test (Table 4.18) revealed that time 1 in the management of depression and irritability was significantly higher than time 2 and time 3, respectively ( $p < 0.01$ ). Equally, significant difference was also observed for time 2 and 3 ( $p > 0.05$ ).

This indicates that the management of anxiety differs across the three time of consultation.

**Table4. 18 Pairwise comparisons, Item 3 (VAS)**

(I) time	(J) time	Mean Difference (I-J)	Std. Error	Sig. <sup>a</sup>	95% Confidence Interval for Difference <sup>a</sup>	
					Lower-Bound	Upper-Bound
1	2	1.321*	.252	.000	.679	1.963
	3	2.489*	.372	.000	1.541	3.436
2	1	-1.321*	.252	.000	-1.963	-.679
	3	1.167*	.258	.000	.510	1.825
3	1	-2.489*	.372	.000	-3.436	-1.541
	2	-1.167*	.258	.000	-1.825	-.510
Based on estimated marginal means						
*. The mean difference is significant at the .05 level.						
a. Adjustment for multiple comparisons: Bonferroni.						

Figure 4.7 further illustrate the differences in the management of anxiety at the different time of consultation. At a glance, it can be observed that time scores change over time (time1 > time 2 and time 3). In addition, it can be observed that the pattern of change between the two groups differs. Overall, the experimental group had lower mean value at time 3 than the control. This indicates that the experimental treatment was more effective in the management of anxiety at the end of treatment when compared against the control.



**Figure 4. 7: Estimated marginal means of distress, Item 3 (VAS)**

#### **4.4.7 Descriptive statistics for Item 4: Energy levels**

As shown in Table 4.18, it can be observed that time 1 (A) had the highest mean presented symptom while time 3 (C) had the lowest mean symptoms. Overall, and at the end of consultation time 3 (C), it can be gathered that the mean value ( $3.53 \pm 1.81$ ) for the experimental group was lower than the control ( $3.53 \pm 2.47$ ). This suggests that the experimental treatment was more effective in the management of perceived participant's energy level at the end of treatment when compared against the control.

**Table4. 19 Descriptive statistics, Item 4 (VAS)**

	Group	Mean	Std. Deviation	N
A levels	Control	5.62	2.755	13
	Experimental	7.06	2.436	17
	Total	6.43	2.635	30
B levels	Control	4.85	2.267	13
	Experimental	5.18	2.298	17
	Total	5.03	2.251	30
C levels	Control	4.54	2.470	13
	Experimental	3.53	1.807	17
	Total	3.97	2.141	30

#### 4.4.7.1. ANOVA assessment for Item 4: Energy level

As shown in Table 4.20, the average score differs significantly between time points beyond the 0.01 interval level: ( $F(1.610, 45.075) = 11.527$ ;  $p < 0.001$ ) with Greenhouse-Geisser adjustment. Partial eta squared = 0.292 representing a large effect. This suggests that time of treatment had a significant differences in both the control and experimental group and the differences between the three time measured was large.

More so, and in respect to the treatment group per time, there was no significant interaction between time and treatment ( $F(1.610, 45.075) = 3.252$ ;  $p > 0.05$ ). Partial eta squared = 0.104 representing a large effect. This indicates that the pattern of distressed measured in the control with time was the same with that measured in the experimental group

**Table4. 20 Tests of within-subjects effects, Item 4 (VAS)**

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Time	Greenhouse-Geisser	78.750	1.610	48.918	11.527	.000	.292
time group *	Greenhouse-Geisser	22.217	1.610	13.801	3.252	.058	.104
Error(time)	Greenhouse-Geisser	191.294	45.075	4.244			

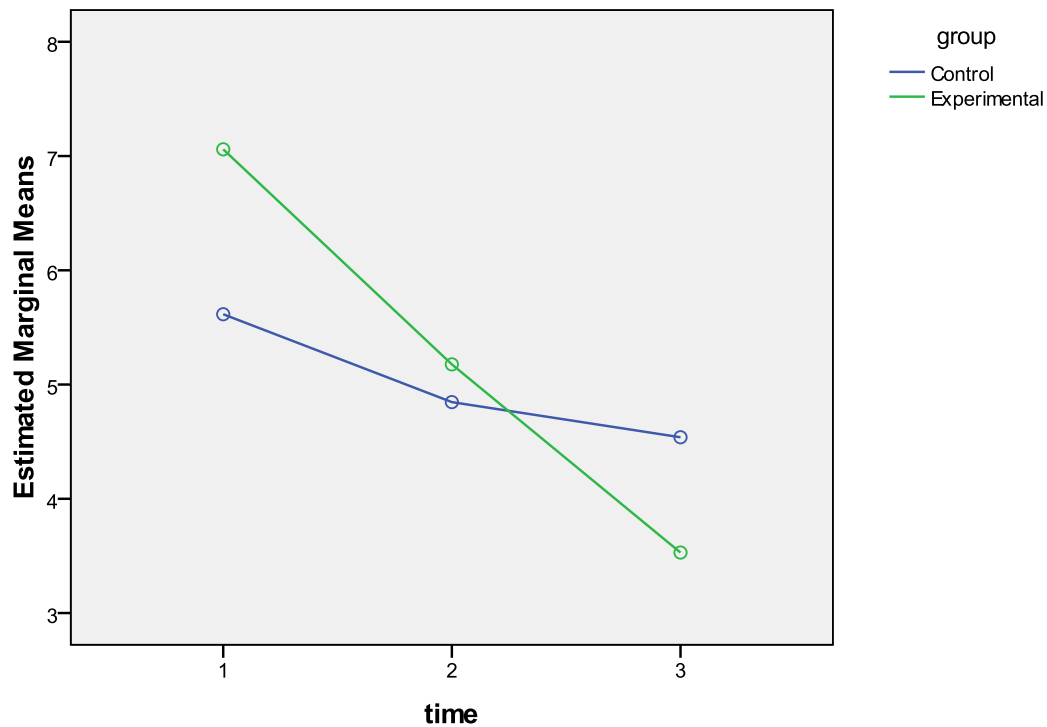
The pairwise comparison test (Table 4.21) revealed that time 1 in the management of energy levels was significantly higher than time 2 and time 3, respectively ( $p < 0.01$ ).

Equally, significant difference was also observed for time 2 and 3 ( $p>0.05$ ). This indicates that the management of energy levels differs across the three time of consultation.

**Table4. 21 Pairwise Comparisons, Item 4 (VAS)**

(I) time	(J) time	Mean Difference (I-J)	Std. Error	Sig. <sup>a</sup>	95% Confidence Interval for Difference <sup>a</sup>	
					Lower-Bound	Upper-Bound
1	2	1.326*	.502	.040	.047	2.605
	3	2.303*	.565	.001	.865	3.741
2	1	-1.326*	.502	.040	-2.605	-.047
	3	.977*	.353	.029	.079	1.876
3	1	-2.303*	.565	.001	-3.741	-.865
	2	-.977*	.353	.029	-1.876	-.079
Based on estimated marginal means						
*. The mean difference is significant at the .05 level.						
a. Adjustment for multiple comparisons: Bonferroni.						

Figure 4.8 further illustrate the differences in the management of energy levels at the different time of consultation. At a glance, it can be observed that time scores change over time (time1 > time 2 and time 3). In addition, it can be observed that the pattern of change between the two groups differs. Overall, the experimental group had lower mean value at time 3 than the control. This indicates that the experimental treatment was more effective in the management of energy levels at the end of treatment when compared against the control.



**Figure 4. 8: Estimated marginal means of distress, Item 4 (VAS)**

#### **4.4.8 Descriptive statistics for Item 5: Sleeping pattern**

From Table 4.22, it can be observed that time 1 (A) showed the highest mean sleeping pattern while time 3 (C) had the lowest mean sleeping pattern. Overall, and at the end of consultation time 3 (C), it can be gathered that the mean sleeping pattern ( $3.35 \pm 2.34$ ) for the experimental group was lower than the control ( $4.31 \pm 2.93$ ). This suggests that the experimental treatment was more effective in the management of the participant's sleeping pattern at the end of treatment when compared against the control.

**Table4. 22 Descriptive statistics, Item 5 (VAS)**

	Group	Mean	Std. Deviation	N
A Sleeping pattern	Control	5.54	2.787	13
	Experimental	6.53	2.741	17
	Total	6.10	2.759	30
B Sleeping pattern	Control	4.77	2.242	13
	Experimental	4.24	2.359	17
	Total	4.47	2.285	30
C Sleeping pattern	Control	4.31	2.926	13
	Experimental	3.35	2.344	17
	Total	3.77	2.609	30

#### **4.4.8.1. ANOVA assessment for Item 5: Sleeping pattern**

The average sleeping pattern differs significantly between time points beyond the 0.01 interval level: ( $F(1.523, 42.637) = 10.746$ ;  $p < 0.001$ ) with Greenhouse-Geisser adjustment. Partial eta squared = 0.277 representing a large effect. This suggests that time of treatment had a significant differences in both the control and experimental group and the differences between the three time measured was large.

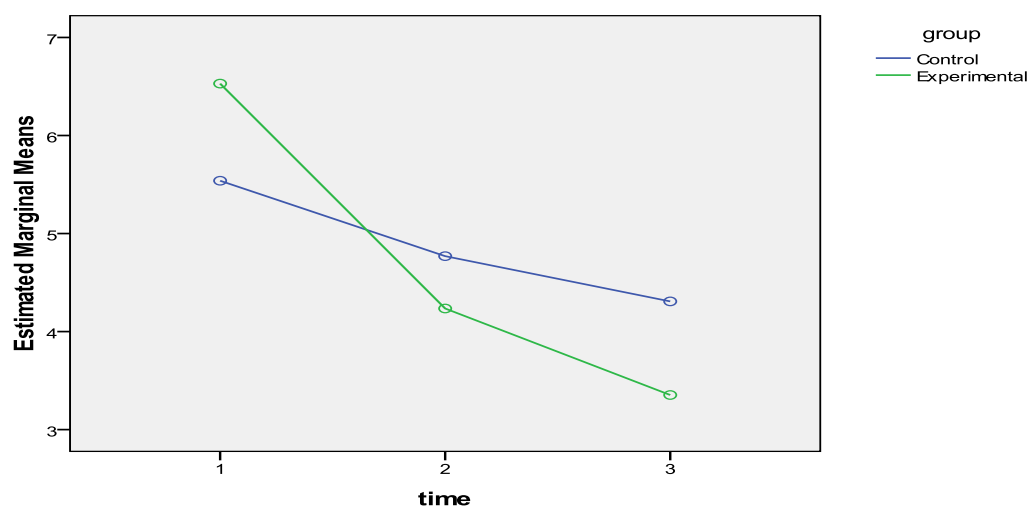
More so, and in respect to the treatment group per time, there was no significant interaction between time and treatment ( $F(1.523, 42.637) = 2.207$ ;  $p > 0.05$ ). Partial eta squared = 0.073 representing a small effect. This indicates that the pattern of sleeping pattern measured in the control with time was the same with that measured in the experimental group

The pairwise comparison test revealed that time 1 in the management of the sleeping pattern was significantly higher than time 2 and time 3, respectively ( $p < 0.01$ ). Equally, significant difference was also observed for time 2 and 3 ( $p > 0.05$ ). This indicates that the management of the participant's sleeping pattern differs across the three time of consultation.

**Table4. 23 Pairwise Comparisons, Item 5 (VAS)**

(I) time	(J) time	Mean Difference (I- J)	Std. Error	Sig. <sup>a</sup>	95% Confidence Interval for Difference <sup>a</sup>	
					Lower-Bound	Upper-Bound
1	2	1.532 <sup>*</sup>	.492	.013	.278	2.785
	3	2.204 <sup>*</sup>	.592	.003	.697	3.710
2	1	-1.532 <sup>*</sup>	.492	.013	-2.785	-.278
	3	.672	.346	.188	-.210	1.554
3	1	-2.204 <sup>*</sup>	.592	.003	-3.710	-.697
	2	-.672	.346	.188	-1.554	.210
Based on estimated marginal means						
*. The mean difference is significant at the .05 level.						
a. Adjustment for multiple comparisons: Bonferroni.						

Figure 4.9 further illustrate the differences in the management of sleeping patterns at the different time of consultation. At a glance, it can be observed that time scores change over time (time1 > time 2 and time 3). In addition, it can be observed that the pattern of change between the two groups differs. Overall, the experimental group had the lowest mean sleeping pattern at time 3 than the control. This indicates that the experimental treatment was more effective in the management of the participant's sleeping pattern at the end of treatment when compared against the control.

**Figure 4. 9: Estimated marginal means of distress, Item 5 (VAS)**



#### 4.4.9 Descriptive statistics for Item 6: Normal lifestyle

As shown in Table 4.24, the average mean value of the participant regarding their lifestyle a week before menses was higher at 1 (A) , while time 3 (C) had the lowest mean value. Overall, and at the end of consultation time 3 (C), it can be gathered that the participant's normal lifestyle before menses was slightly higher for the experimental group ( $3.29 \pm 2.29$ ) than the control ( $3.23 \pm 1.92$ ).

**Table4. 24 Descriptive statistics, Item 6 (VAS)**

	Group	Mean	Std. Deviation	N
A Normal lifestyle a week before menses	Control	6.69	2.250	13
	Experimental	6.29	2.756	17
	Total	6.47	2.515	30
B Normal lifestyle a week before menses	Control	4.92	1.656	13
	Experimental	4.06	2.358	17
	Total	4.43	2.096	30
C Normal lifestyle a week before menses	Control	3.23	1.922	13
	Experimental	3.29	2.285	17
	Total	3.27	2.100	30

##### 4.4.9.1. ANOVA assessment for Item 5: Sleeping pattern

As shown in Table 4.25, the participants normal lifestyle before menses differs significantly between the three time points beyond the 0.01 interval level: ( $F(1.478, 41.387) = 27.065$ ;  $p < 0.001$ ) with Greenhouse-Geisser adjustment. Partial eta squared = 0.492 representing a large effect. This suggests that time of treatment had a significant differences in both the control and experimental group and the differences between the three time measured was large.

More so, and in respect to the treatment group per time, there was no significant interaction between time and treatment ( $F(1.478, 41.387) = 0.547$ ;  $p > 0.05$ ). Partial eta squared = 0.073 representing a small effect. This indicates that the lifestyle of the participants before menses measured in the control with time was the same with that measured in the experimental group.

**Table4. 25 Tests of within-subjects effects, Item 6 (VAS)**

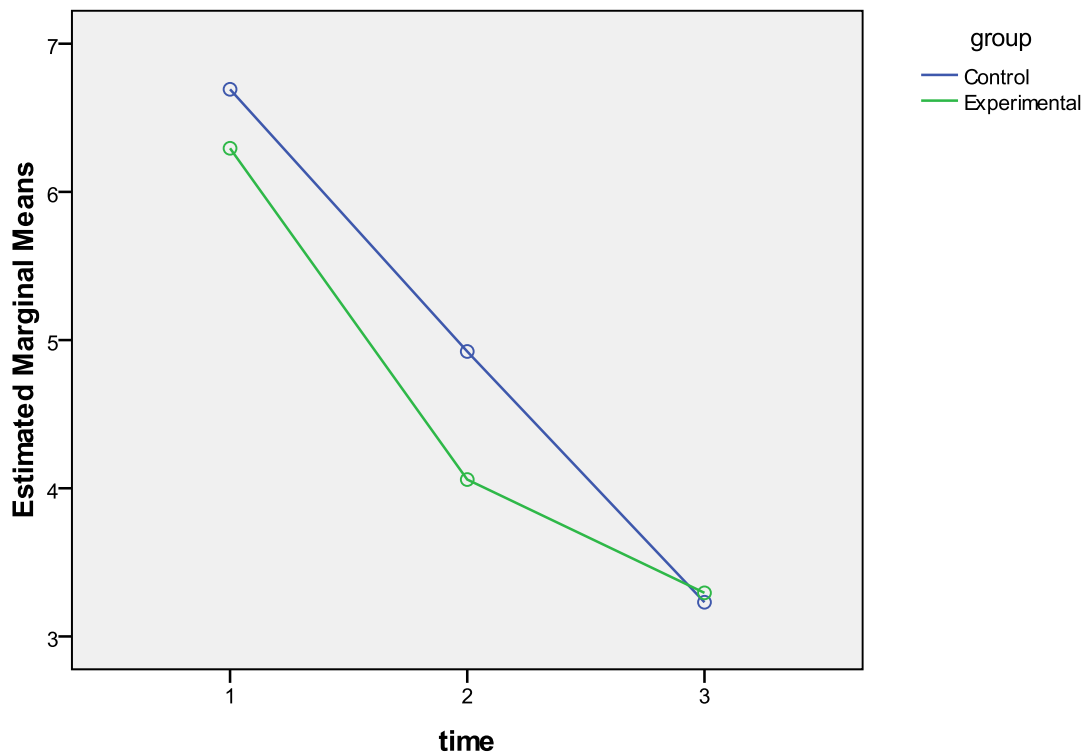
Source		Type III Sum of Squares	Df	Mean Square	F	Sig.	Partial Eta Squared
Time	Greenhouse-Geisser	156.725	1.478	106.031	27.065	.000	.492
time * group	Greenhouse-Geisser	3.169	1.478	2.144	.547	.530	.019
Error(time)	Greenhouse-Geisser	162.142	41.387	3.918			

The pairwise comparison test shown in Table 4.26 revealed that time 1 in the management of the lifestyle before menses was significantly higher than time 2 and time 3, respectively ( $p < 0.01$ ). Equally, significant difference was also observed for time 2 and 3 ( $p > 0.05$ ). This indicates that the management of the participant's lifestyle before menses differs across the three time of consultation.

**Table4. 26 Pairwise comparisons, Item 6 (VAS)**

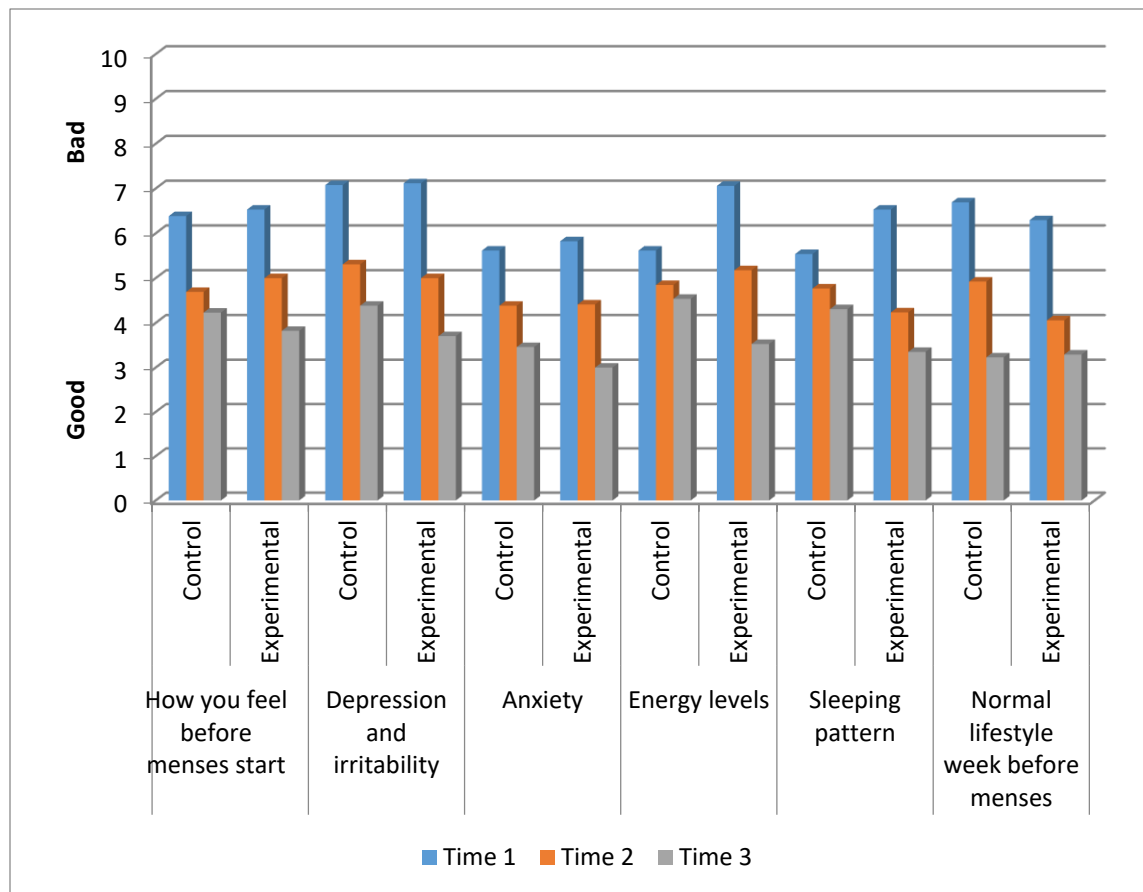
(I) time	(J) time	Mean Difference (I- J)	Std. Error	Sig. <sup>a</sup>	95% Confidence Interval for Difference <sup>a</sup>	
					Lower-Bound	Upper-Bound
1	2	2.002 <sup>*</sup>	.425	.000	.919	3.086
	3	3.231 <sup>*</sup>	.552	.000	1.826	4.636
2	1	-2.002 <sup>*</sup>	.425	.000	-3.086	-.919
	3	1.229 <sup>*</sup>	.323	.002	.407	2.050
3	1	-3.231 <sup>*</sup>	.552	.000	-4.636	-1.826
	2	-1.229 <sup>*</sup>	.323	.002	-2.050	-.407
Based on estimated marginal means						
*. The mean difference is significant at the .05 level.						
a. Adjustment for multiple comparisons: Bonferroni.						

Figure 4.10 further illustrate the differences in the management of lifestyle pattern before menses at the different time of consultation. At a glance, it can be observed that time scores change over time (time1 > time 2 and time 3). In addition, it can be observed that the pattern of change between the two groups differs. For example, the mean value for the control for time 1 and 2 were higher than the experimental group. In contrast, the mean value for the control and experimental group was more or less the same at time 3.



**Figure 4. 10: Estimated marginal means of distress, Item 6 (VAS)**

Figure 4.11 further depicts the graphical representation in the management of PMDD over three consultation time (1-3) with VAS. As seen below, a consistent reduction in the presented symptoms was noted for both the control and experimental group. More so, apart from the “normal lifestyle before menses, the experimental treatment showed better management of the symptoms at the end of the treatment.



**Figure 4. 11: Graphical representation of each of the six symptoms over time periods 1-3 for the effect of treatment (VAS)**

## 4.5 Conclusion

In Summary, and from the section above, it was observed that the treatment of PMDD differs significantly over three consultation times (1-3) when measured using both KPD and VAS. Although the results failed to show statistically differences between the control and experimental group in the management of PMDD, however, the mean value measured in the experimental group were consistently lower than the control. Overall, this section did not conclusively show that homoeopathic mother tincture was more effective in the management of PMDD. The subsequent chapter will provide a rigorous discussion of the study results.

## CHAPTER FIVE: DISCUSSION OF THE RESULTS

### 5.1 INTRODUCTION

The study aimed to compare and determine the efficacy of a Homoeopathic mother tincture complex (*Vitex agnus castus*, *Melissa officinalis* and *Valeriana officinalis*) treatment to a placebo in the management of Premenstrual Dysphoric Disorder.

#### 5.1.1 DEMOGRAPHICS

##### 5.1.1.1 Race

29 participants were black (97%) and 1 participant was white (3 %). The demographics are somewhat related to the location of the study, the setting of the study was in KwaZulu-Natal and according to the 2011 census in KZN there are 86.8% of black ,7.37% Indians, 4.18% white and 1.38% coloured (Lehohla 2011). No documented studies that show that PMDD is a condition that is more prevalent in one race than the other therefore the race demographics results on this study cannot be compared, even the rationale stipulated above does not have a significant interpretation.

##### 5.1.1.2 Age, marital status and occupation

The average age of participants was 23 years, unmarried, and students. Results are within the range of the incidence reports with regards to age which is women of reproductive age. Age-specific fertility rates are defined using the number of women in each age group and the number of births to women in that age group. Women of reproductive age refers to all women aged 15–49 years. This study only included females from 18 years to 35 years. In retrospect, the study should have included a more for broader range. Our study illustrates that ethical considerations to not include participants younger than 18 years may have excluded. These demographics could be explained by the location of the study which is at a university. Adverts were placed around the university campus and consulting hours were from 8am to 5pm which explains why most participants were students and not workers. Students were able to work around their time

table as compared to workers as the consulting hours were during work hours. Also, the location was convenient for students based at DUT more than other potential participants. Ninety seven percent of participants were single and black and only one person (3%) was married and white in this study.

#### **5.1.1.3 Home Language**

Figure 4-3 shows that 90% of the participants were isiZulu speaking and 3.3% English, IsiXhosa and Siswati. Out of the 11 official languages in South Africa, Lehohla (2011) shows that the most spoken home language in KZN is the Zulu language, the adverts spoke to IsiZulu speaking population more as the translated version was only available in IsiZulu. As much as this might have no bearing on the results of the study in terms of the objectives, the current study suggests that the consultation and the understanding of scales was effective as the consultation and the processes were conducted in participants language of preference. However, having stated this factor it can also be argued that direct translation of one language to another may not always be possible and accurate and hence the scales could potentially lose the meaning.

### **5.2 Discussion of results from scales**

To fully compare the effectiveness of the treatment, changes in the participants PMDD were recorded in both the Visual Analogue Scale (VAS) and Kessler Psychological Distress scale (KPD) scale. The formulated hypotheses was accepted on the bases of the study results. The mixed factorial ANOVA results demonstrated that there was no statistical significance differences between the treatment and control group measured in both KPD and VAS ( $p > 0.01$ ).

#### **5.2.1 Visual Analogue Scale (VAS) Results**

The following factors were considered as a means of measurement: how participants feel before their menses; their level of depression and irritability; level of anxiety and energy levels; and sleeping patterns and lifestyle a week before menses. It was observed that both groups showed the decrease of the symptoms like depression and irritability when compared to baseline and consultation 3, however the experimental group showed

greater reduction of symptoms than control group. The reduction of these symptoms, however, do not show a statistical significance. The researcher argues that even though this reduction may not be statistically significant it is still worth noting because there are a number of factors that could potentially influence the completion of the scales and ranking the reduction of symptoms. The researcher suggests that the symptoms that are qualitative in nature must be measured using an appropriate tool which is also qualitative. The researcher also suggests that measuring hormones using blood samples taken before and after the completion of the study could have potentially yielded different results as the homoeopathic complex was working on the organic level. It is also important to note that anxiety levels also decreased in both groups however more so in the experimental group which started with a higher mean of 5.82 when compared to control at 5.62. However, the final rating at consultation 3 was 3.00 for experimental and 3.46 for control group. The difference, even though not statistically significant, is noteworthy as it concurs with previous studies that showed the efficacy of *Vitex agnus castus*.

Energy levels also improved from baseline compared to both groups. It is also notable that the experimental group started with higher scores and ended with lower scores for mean valued compared to control group which is evidence that the experimental group proved to be superior than the placebo even though these values do not show statistical significance. Control group started at consultation 1 with 5.62 and experimental group was 7.06. On consultation 3 control group was 4.54 whereas the experimental group was 3.53. This is validated by the statistical analysis which showed that even sleep patterns and normal lifestyle improved after the interventions. Yet, the results favoured the experiential group as it showed a higher reduction of the symptoms in the VAS than the control group. Now these results are proving that there is an effect of the tested complex. It would be interesting to investigate the extent over a longer duration of time with a bigger sample size. Our that the results may have a more statistically significant number than the results shown in this study. Having stated that, it is also critical to note that the number might not show the significance but the improvement it brought to the participants who were suffering from this condition is remarkable. The researcher had stated earlier in Chapter 2 the affinity of the ingredients in the experiential complex.

*Vitex agnus castus* has an effect on hormones that regulate women's reproductive cycles. According to Katz (1995), *Vitex agnus castus* has proven to be effective with respect to all psychic and somatic symptoms of the heterogeneous and multifaceted PMS. A review on complementary/alternative therapies for PMS by Stevenson and Ernst (2001) found that the herbal medicine *Vitex agnus castus* showed dramatic improvements during the first cycle of treatment and that there was stability during the remaining two cycles of the study. The researcher concurs with other researchers that multicentre trials be conducted since there is obviously limited evidence that supported the efficacy of alternative medicine interventions in controlling PMS/PMDD.

The researcher also assumes that the combined effect enhanced the ingredients better as they had affinity for different areas. As it has been stated previously, *Melissa officinalis* is used for stress, anxiety, insomnia, indigestion, colic and depression. It enhances memory and has calming effects (Maguire and Mody 2012). This can also be said about *Valeriana officinalis*, which is most commonly used for sleep disorders, for conditions connected to anxiety and psychological stress including nervous asthma, hysterical states, excitability, and fear of illness (hypochondria), headaches, migraine, and stomach upset. It is also indicated for over sensitiveness and nervous affections with changeable disposition (Vermeulen 2001).

Furthermore, Kennedy *et al.* (2006) conducted a study on the anxiolytic effects of a combination of *Melissa officinalis* and *Valeriana officinalis* on laboratory induced stress. The study showed that a 600mg dose of the combination ameliorated the negative effects of the Defined Intensity Stressor Simulation (DISS) battery on ratings of anxiety. However, the highest dose (1800mg) showed an increase in anxiety that was less marked but which reached significance during one testing session. It is therefore not surprising that there was a decline in symptoms and that it was greater in the experimental group even though this is contrary to Bhatia (2009) who states that a homoeopathic complex is never proved as an entity. The medicine interaction and their combined effects are not known; it is possible that one of the ingredients cancelled the effect of the others. If this was the case



then there would have not been a decline in symptoms especially in the experimental group.

### **5.2.2 Kessler Psychological Distress scale (KPD) scale**

With regards to the KPD data, it was gathered that time of treatment significantly improved the condition of PMDD ( $p < 0.05$ ). As reported in Table 4.6 and 4.7, the distress at time K10A ( $29.036 \pm 1.200$ ) is significantly higher than at times K10B ( $20.301 \pm 1.334$ ) and K10C ( $17.292 \pm 1.146$ ),  $p < 0.0005$  in each case. Distress at time K10B was significantly higher than at time K10C ( $p < 0.05$ ),  $p = 0.041$ . Examination of the between-subject effects shows that treatment (group) does not significantly affect distress scores. Figure 4-7 shows estimated marginal means of distress between the two groups (control and treatment), the figure shows a consistent reduction of distress from the first to last consultation in both groups with experimental group slightly less distressed than the control group at the last consultation even though it is statistically insignificant  $p = 0.41$ . Figure 4-8 shows the results of both groups before and after treatment.

Of importance, a constant reduction of symptoms was observed which suggested effectiveness of the treatment in the management of symptoms. The time factor can be argued both ways as to whether it was a limitation to this study as other PMDD studies have been done in 6-8 weeks. Grohol (2016) states that antidepressants which are often the first line of defence against PMDD takes about 6-8 weeks to show effectiveness in treatment. Therefore, time limitation cannot be used as the only factor for the statistical significance even though this is a chronic disease may require a longer time of treatment administration. Since homoeopathy is gentle and quick to act as per the philosophy, the researcher advocates for homoeopathy as there were no noted side effects experienced by participants during the study period. Thus making this form of therapy more preferential. The researcher suggests that had the treatment been on-going for at least a year there would possibly be a greater reduction of symptoms as the results showed that the scales were still dropping in numbers by the third consultation. Other factors that should have been considered were the iron levels, which is directly linked to energy and concentration levels together with dietary habits like skipping meals, and bad eating

habits that also have a direct link to fatigue and mood. In conclusion, the salient point of this study suggests that the change between the control and experimental group is an indication that there is more that can be done through alternative medicine.

### **5.2.3 The placebo effect**

In both scales both, the treatment and placebo group improved even though there was no statistical significance between them. In this study, the placebo was used as a control to determine the efficacy of the homoeopathic tincture in the management of PMDD. Placebo effect is a genuine psychobiological phenomenon attributed to the overall therapeutic context (Miller and Kaptchuk 2008). The participants made time to consult with the researcher in the hope that they would get relief of the symptoms; that alone could have contributed to the placebo effect, which concurs with Kaptchuk and Miller (2002). During the consultations in the current study, the participants could ask questions, and after the consultation, the researcher gave every participant her personal contact details to call at any time if they had any questions regarding the research. This could have played a role in the improvement of patients' symptoms. Kaptchuk and Miller (2002) states that the clinic interaction can dramatically enhance the effect of pharmaceuticals. The participants had to fill in the scales with the researcher in the room so it was possible that the participants were pleasing the researcher or that they felt pressured that they had to say symptoms were better because they were being watched. This is called the Hawthorne effect, where participants alter their behaviour as a result of being watched (Leonard 2008).

### **5.3 Conclusion**

Based on the results the first, second and third null hypothesis are accepted. There seems to be contradictory evidence in the literature regarding the test substance and more clinical trials of PMDD are required to substantiate the findings. It is also noted that due to the limitations of the study, a generalisation cannot be made based on this sample size and just one location of the study. More homoeopathic mother tincture complex clinical trials are needed to offer guidelines for the prescription of such a tincture in the future, and thus serve as scientific and clinical verification of the substance.

## CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

### 6.1 CONCLUSION

This study sample consisted of 30 consenting females between the ages 18 and 35. The aim of the study was to compare and determine the efficacy of a homoeopathic mother tincture complex (*Vitex agnus castus*, *Melissa officinalis* and *Valeriana officinalis*) compared to a placebo in the management of Premenstrual Dysphoric Disorder. Concerning the Kessler psychological distress scale and the visual analogue scale, both groups improved but there was no statistical difference between them and therefore perhaps the consultation had an effect, which then needs to be investigated further.

Viewing the results of this trial retrospectively, some of the research areas could have been refined to allow more positive outcome. Most participants had been suffering from PMDD for many years and months, therefore their condition had been longstanding and of chronic nature thus requiring treatment over a longer period. As such, the duration of this study was too short and future trials should be carried out over a longer period to allow medication to act fully. A larger sample size for future research is suggested, in order to obtain greater statistical accuracy.

A characteristic problem in clinical studies 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. Additionally, the placebo responses are augmented by the very nature of this study, as the placebo targets the patient's superficial perception and expectation. 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 an exceptional level. This is reason enough why the results of this study are important even though they did not prove to be statistically significant but rather proved that there was a notable decline of symptoms of PMDD.

## **6. 2 LIMITATIONS OF THE STUDY**

The study recruited 30 participants:

- Limited to KwaZulu-Natal province.
- Only participants with regular periods were recruited.
- Due to the nature of the study, patient compliance was important. The researcher had to depend on the participants to remember the exact information of their symptoms when filling in the scales.
- The assumption was made that participants took the medication as directed by the researcher during the consultation. It is possible that not all of the participants followed through with the instructions.
- Laboratory blood test results, including a female hormonal screen, could have shown objective changes experienced by the participants.
- Short duration; possibly a longer study would have proved more beneficial as this study was only three months.
- Given the chronicity of the condition perhaps a longer study period would show statistical differences.
- A larger sample size could have yielded better data.

## **6.3 RECOMMENDATIONS**

- A larger sample size be used in order to obtain greater statistical accuracy.
- Research to be conducted in a different province.
- Increase in the duration of the study.
- Research comparing homoeopathic mother tincture with a homoeopathic simillimum in the treatment of PMDD.
- Keeping diaries with scales might have improved accuracy when filling in the scales.

## **6.4 FURTHER RESEARCH**

A qualitative data study on this topic should be conducted for comparability of results with this quantitative study that was conducted.

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## APPENDIXES

### Appendix A: IREC full approval



12 September 2017

IREC Reference Number: **REC 27/16**

Ms B N S Sukati  
P.O. Box 3516  
Mbabane  
Swaziland

Dear Ms Sukati

**The efficacy of a Homoeopathic mother tincture complex (*Vitex agnus castus*, *Melissa officinalis* and *Valeriana officinalis*) in the management of Premenstrual Dysphoric Disorder**

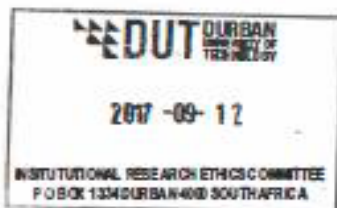
The Institutional Research Ethics Committee acknowledges receipt of the late submission of your gatekeeper permission letters. Provisional approval was granted to you on 17 May 2016. Please be advised that you were required to submit the necessary gatekeeper permissions to the IREC before commencing with data collection, failure to do so could result in penalty.

Please note that **FULL APPROVAL** is granted to your research proposal.

Yours faithfully,



Professor J.K. Adam  
Chairperson: IREC

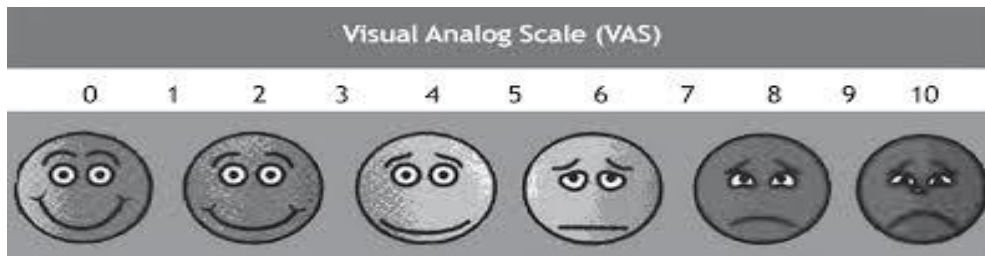


## Appendix B(a): Visual analogue scale form (VAS) (English)



### Visual Analogue 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:

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?

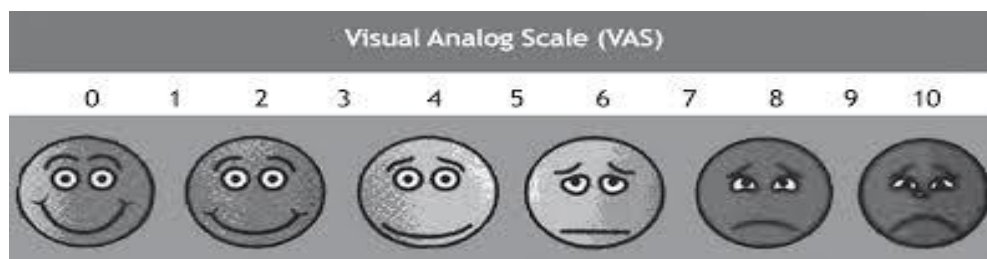
(Adapted from the DSM-IV 1995, Google images)

Appendix B(b): Visual Analogue Scale Form (VAS) (isiZulu)



Visual analogue scale form (VAS) –isikali

(Ngokwe DSM-IV 1995 no-Crichton 2001)



Kuloluhlu lwezimpawu nemiboniso langezansi zihluze ukuthi wena uzizwa kanjani ngokuthi ubuke isithombe sobuso obona ukuthi sichaza kancono indlela ozizwa ngayo wena.

1. Ngaphambi kokuthi uye esikhathini uzizwa kanjani zihluze?
2. Hluza ukudangala kwakho nokuchasuka kwakho?
- 3 Hluza ukuthathazela kwakho?
4. Hluza umdlandla wakho?
5. Kanjani ukulala kwakho?
6. Injani indlela uzizwa ngayo esikhathini esingange sonto ngaphambi kokut  esikhathini

(ithathwe kwi DSM-IV 1995, isithombe zithathwe ku Google

## Appendix C: 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)

	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)
Please tick the answer that is correct for you:					
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

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.

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## Appendix D(a): Information letter for participants (English)



### 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 tincture in the management of Premenstrual Dysphoric Disorder (PMDD).

Principal Investigator/s/researcher: Ms Behlulile Nonsikelelo Stoppy Sukati, 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 tincture in the management of Premenstrual Dysphoric Disorder (PMDD). PMDD as described by (DSM-V 2013) is characterised 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 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. 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 tincture 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 Behlulile Sukati (Student) Telephone no: 073 662 3843

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 D(b): Information letter for participants (English) (IsiZulu)



Incwadi yolwazi yalabo abazozibandakanya kucwaningo (IsiZulu)

INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC)  
LETTER OF INFORMATION

Ngiyakubingelela

Siyabonga ngokuvuma ukuzibandakanya kwakho kulolu cwaningo

Isihloko socwaningo: Ukubaluleka kwemithi ehlanganisiwe yeHomoeopathy okuyi simillimum ekusizeni kwisilumo.

Umcwaningi: Ms Behlulile Sukati, B.Tech. Homoeopathy

Abaphathi hlelo: uDkt. J. C. Ngobese-Ngubane, M. Tech. Hom. (Umpathi wocwaningo)

Dkt I. Couchman, M. Tech. Hom. (Isekela likamphathi wocwaningo)

Incazelo nenhloso yalolucwaningo: Inhloso yalolucwaningo ukuveza ukubaluleka kwemithi ehlanganisiwe ye-Homoeopathy okuyi-simillimum ekusizeni ngesilumo. Isilumo nje ngoba sichazwa kwi ncwadi (DSM-V 2013) sinomphumela wokuwokuhlisa umdlandla wokuqeda usuku, ukungabi nomusa nokwenza izinto ngendlela enolaka. Uye umuntu azizwe engakunameli ukuya emsebenzini, esikoleni noma ukuhlanganyela nabangani bakhe. Ukuba nenkinga ngokunganaki, ukukhathala masisha. Ukushintsha indlela odla ngayo, ukuba nolaka, ukuthandiswa ukudla okuthize, ukuqwasha noma ukulala kakhulu.

Indlela uhlelo oluzohamba ngayo: kwinxoxo ozobanayo nomcwaningi yilapho imininingwana ephathelene nesilumo sakho wena muntu ozibandakanyayo nocwaningo izoqoshwa khona loku kuzo kwenzeka eDurban

University of Technology (DUT) lapha eclinic yakwa Homoeopathy yasemini (HDC). Ucwangingo luzothatha izinyanga ezinathu okuzoba amasonto ayi 12 uzobonana nomcwangingi kathathu kulesikhathi sezinyanga ezinathu. Umbona Kanye njalo ngenyanga ngemuva kokuya esikhathini. Ukubonana nomcwangingi okokuqala kuzothatha isikhathi esiyi hora elilodwa ubude bese kuthi okwesibili nokwesithathu kube imizuzu awu 30 ubude. Kuzodingeke umuntu ozibandakanyayo nocwangingo aqale agcwalise ifomu lesivumelwano kuqala. Bese ahlolwe umcamo ukuqinisekisa ukuthi akazethwele yini ngoba abavumelekile abantu abazethwele kulolucwangingo. Zobe sewugcwalisa isikali ozochazelwa ngaso lesikali sithatha imizuzu engama 10 ukusiqeda. Lesikali usigcwalisa njalo mawuzobonana nomcwangingi.

Non-participation: Ukungazibandakanyi: awuphoqiwe ukuthi ube yingxenywe yalolucwangingo. Ukuzibandakanya kwakho kuwukuzinikela kwakho. Ukungazibandakanyi kwakho ngeke kuphazamise usizo olutholakala ehomoeopathic day clinic.

Ubungozi kulowo ozibandakanyayo: Abuko ubungozi obaziwayo ozohlangabezana nabo mawubonane neHomoeopath.

Inzuzo: Le mininingwana esiyithola kuwe ngesilumo sakho izosiza sifike esiphethweni ngokubaluleka kwe mithi ehlanganisiwe ye- homoeopathy simillimum ekusizeni ngesilumo nawe uthole ukusizwa kancono isilumo nezimpawu zaso.

Kulindlekeni kozibandakanyayo? Uzonikwa umuthi owu 50 ml. uzothatha amaconsi ayishumi emlonyeni ngaphansi kolwimi kabili ngosuku sonke lesikhathi usangaphansi kocwangingo. Uyacelwa unga sebenzisi eminye imithi yesilumo ngalesikhathi ungaphansi kocwangingo ngoba lokho kungaphazamisa imiphumela yocwangingo. Indlela yokuthatha umuthi uzotshelwa ngayo. Kunamathuba awu 50% wokuthi uzofakwa kulaba abazothola umuthi qobo noma ube kulaba abazothola amaconsi sifaniso angenamuthi. Kodwa mawufakwe kulaba abazothola amaconsi sifaniso ekigcineni kocwangingo uzonikwa umuthi qobo nawe.

Izizathu zokushiya Ucwangingo kothe wazibandakanya: Uvumelekile ukuphuma ocwangingweni noma inini ngaphandle kwesijeziso.

Inani nokubiza kwalolucwangingo: Akukhokhwa mali futhi awulindlekile ukuba ukhokhe ngokuzibandakanya kulolucwangingo kumahala.

Ukuphepha nefihlo: Uyacelwa ungabhali imininingwana yakho kwi sikali yonke imininingwane ezotholaka izoba yimfihlo ukuthi ekabani izoba seyibekwa endaweni ephephile iminyaka emi 5.

Ezokuphepha: Abukho ubungozi umuntu azoba kubo ngalesikhathi socwaningo ngoba lolucwaningo alunabongozi obaziwayo.

Abantu ongaxhumana nabo noma ingaziphi izinkinga ngalesikhathi socwaningo.

Ms Behlulile Sukati (Umcwaningi) 073 662 3843

Dokotela J. C Ngobese-Ngubane (umphathi hlelo) 031 373 2484

Dokotela I Couchman (usekela mphathi hlelo) 031 373 2482

Institutional Research Ethics administrator 031 373 2900

Izikhaziso ungazidlulisela ku DVC: TIP. FOTIENO 031 373 2382 [dvctip@dut.ac.za](mailto:dvctip@dut.ac.za)

## Appendix E(a): Consent form for participants (English)



### 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

## Appendix E(b): Consent form for participants (isiZulu)



Incwadi yesivumelwano (IsiZulu )

INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC)

Isivumelwano sokuzibandakanya nocwaningo:

Ngiyavuma ukuthi umcwaningi \_\_\_\_\_ (igama lomcwaningi) ungichazele ngesimo, nendlela lolucwaningo elizohamba ngayo, imiphumela nobungozi balolucwaningo

Inombolo ye-ethics clearance \_\_\_\_\_.

Ngiyitholile nencwadi yemininingwane ebalulekile ngayifunda ngayizwisisa kahle.

Ngaziswa ukuthi imiphumela yalolucwaningo, Kanye neminingwane yami yobulili, iminyaka yami, usuku lwami lokuzalwa nokulashwa kwami kuzoba into imfihlo kuhlelo lokuqoshwa kwalolucwaningo.

Kwizinto ezidingekayo kulolucwaningo, Ngiyavuma ukuthi imininingwane abayiqhophayo ngami kulolucwaningo linga setshenziswa kwi-computerised system uyena umcwaningi.

Noma yinini ngaphandle kwesijeziso ngingahoxa nesivumelwano sami ngokuzibandakanya kwami kulolucwaningo.

Ngibe nesikhathi esanele sokubuza imibuzo lapho ngingaqondi khona mayelana nalolu cwaningo ngokuzinikela kwami Ngiyavuma ngikulungele ukuzibandakanya nalolucwaningo. Ngayaqonda ukuthi imiphumela emisha etholakala ngalesikhathi salolucwaningo engaphathelana ngokuzibandakanya kwami izokwenza into etholakalayo nakimina. Igama lomuntu ozibandakanyayo \_\_\_\_\_ (amagama amakhulu) Usuku \_\_\_\_\_

isikhathi \_\_\_\_\_ sayina \_\_\_\_\_ noma ubeke isithupha sakwesokudla.

Mina \_\_\_\_\_ (igama lomcwaningi) Ngiyavuma ukuthi lo muntu ozibandakanyayo ngenhla ngimtshelile ngesimo, nendlela lolucwaningo elizohamba ngayo nobungozi bocwaningo. Igama lomfundi owenza Ucwaningo \_\_\_\_\_ (amagama amakhulu) Usuku \_\_\_\_\_ isikhathi \_\_\_\_\_

sayina \_\_\_\_\_ Igama likafakazi \_\_\_\_\_ (amagama amakhulu)

Usuku \_\_\_\_\_ isikhathi \_\_\_\_\_ sayina \_\_\_\_\_

Igama Lomeli (mekhona) \_\_\_\_\_ usuku \_\_\_\_\_ sayina \_\_\_\_\_

## Appendix F: The inclusion criteria for PMDD as stated by the DSM-V



### 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

Participants must be females between the ages 18-35 years.

Participants must be living around Durban –KwaZulu-Natal.

Participants must be willing to follow study requirements.

Participants who are not on any treatment for PMDD.

Participants are not having a chronic medical or mental condition.

Participants must maintain her normal lifestyle during the study.

Participants who are not pregnant or intending to conceive for the duration of the study.

Participants who have not had surgery in the past six weeks.

Participants who are not on any recreational drugs.





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

HOD: Homoeopathy Department  
P. O. Box 3516  
Mbabane  
Swaziland

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 Miss. Behlulile Sukati (20707749). 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 mother tincture complex (*Vitex agnus castus*, *Melissa officinalis* and *Valeriana officinalis*) in the management of Premenstrual Dysphoric Disorder.

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 scal 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.

Miss. Behlulile Sukati (20707749) – Researcher: 0736623843

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

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

**Appendix G(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 3516  
Mbabane  
Swaziland

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 Miss. Behlulile Sukati (20707749). 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 mother tincture complex (*Vitex agnus castus*, *Melissa officinalis* and *Valeriana officinalis*) in the management of Premenstrual Dysphoric Disorder.

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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Miss. Behlulile Sukati (20707749) – Researcher: 0736623843

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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 G(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 3516  
Mbabane  
Swaziland

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 and staff**

Thank you for reading this letter. My name is Miss. Behlulile Sukati (20707749). 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 mother tincture complex (*Vitex agnus castus*, *Melissa officinalis* and *Valeriana officinalis*) in the management of Premenstrual Dysphoric Disorder.

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.

---

Miss. Behlulile Sukati (20707749) – Researcher: 0736623843

---

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

---

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

## Appendix G(d): Application letter for increase of research budget



P.O. Box 3516  
Mbabane  
SWAZILAND

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

Dear Professor Moyo

### **Application Letter for increase of research budget**

Thank you for reading this letter. My name is Ms Behlulile Sukati (20707749). I am currently registered for M. Tech. Homoeopathy and I am requesting an increase of budget for my research study with an additional amount of **R5000**. Most of my research budget is for editing services and statistical analysis. The remaining just barely covers the medication for the study. The title of my study is: The efficacy of a Homoeopathic mother tincture complex (*Vitex Agnus Castus*, *Mellisa officinalis* and *Valerian officinalis*) 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 is 3 months, with only 3 consultations. 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 they 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 15-20 minutes. These scales will be completed before each consultation. Randomisation will be drawn up by an independent staff member who is a qualified and registered homoeopath and technician for the Homoeopathy department. A sample size of 35 consenting participants will be evenly distributed between the homoeopathic mother tincture and Placebo groups. Homoeopathic remedies treat holistically and cures rapidly, yet gently and permanently restores health.

Yours sincerely.

Ms. Behlulile Sukati (20707749)-Researcher 073 662 3843

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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 (Co-supervisor) - 031 3732482 ([Ingrid@dut.ac.za](mailto:Ingrid@dut.ac.za))



**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. Behlulile Sukati (20707749). I am currently registered for M. Tech. Homoeopathy and I am requesting to conduct my research study at the Homoeopathic Day Clinic (HDC). The title of my study is: The efficacy of a Homoeopathic mother tincture complex (*Vitex agnus castus*, *Melissa officinalis* and *Valeriana officinalis*) in the management of Premenstrual Dysphoric Disorder.

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.

---

Miss. Behlulile Sukati (20707749) – Researcher: 0736623843

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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 H: Quotation for editing



## Rookmoney Thakur

Btech: Journalism, M.Phil: Quality Management  
Ph.D candidate (DUT)

92 Victoria Road  
Hillary/Durban 4094  
031-464 5041/078-544 2461

Email: maleni.thakur@gmail.com

### LETTER TO SUPERVISOR AND QUOTATION

Date: 25 January 2018

**For:** Ms Behlulile Nonsikelelo Stoppy Sukati (20707749)

**Re:** Proof -reading and editing of M. Tech: Hom dissertation.

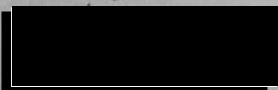
I proof-read, language edit, reference edit, layout edit and meaning edit i.e. change wording to sharpen and/or clarify the meaning of sentences as appropriate. I am presently pursuing a doctorate degree at the Durban University of Technology (D.Phil.: Peace Studies). My first degree, which I obtained at DUT, was a Nat.Dip: Journalism (1995). I obtained a B.Tech: Journalism (2011). I went on to complete an M.Phil. Quality Management (2016). I was employed as a writing tutor at DUT (M.L Sultan Campus) for the year 2015.

My rate is calculated per received page (12 pt. font; 1.5-line spacing) including the front pages but excluding appendixes and is R20 per page, including the List of References.

Quotation for the services rendered to Ms Sukati is **R1 880.00** (94 pages @ R20).

Should you have any enquiries please feel free to contact me.

Best Regards

  
Mrs. R. Thakur

Appendix I(a): Quotation for statistics



Quotation for statistics

**Gill Hendry** B.Sc. (Hons), M.Sc. (Wits)

Mathematical and Statistical Services

Cell: 083 300 9896

email : hendryfam@telkomsa.net

March 2015

I charge for all work done on an hourly rate of R200 per hour.

Regards

Gill Hendry





## 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 22.0 (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: Miss. Behlulile Sukati – 0736623843

OR

Clinic reception: 031 373 2041

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



### German Homoeopathic Pharmacopoeia – preparation for homoeopathic complex (Method 10)

The test complex was made of equal parts of:

Melissa officinalis $\varnothing$ HAB 3A	62% v/v
Valeriana officinalis $\varnothing$ =D1 HAB 4A	68% v/v
Vitex Agnus castus $\varnothing$ =D1 HAB 4A	68% v/v

The HAB is the German Pharmacopoeia method, also often written as GHP.

Once the mixture was homogenous it was decanted into 50 ML amber glass dropper bottles.

## Appendix L: 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:

If no symptoms for any section of the case, write NAD (No Appreciable Disease) in the space provided.

[illegible]


PAST MEDICAL HISTORY: Childhood illnesses, vaccinations, hospitalisation, surgery. Accidents. Any other chronic illnesses still currently active e.g. hypertension, diabetes, asthma. If a patient is a child below 10 years of age, ask about history of mother's pregnancy and the childbirth. If appropriate, ask about the circumstances of the birth – wanted child? Father present and supportive? Family supportive? Etc.


Allergies: \_\_\_\_\_  
 \_\_\_\_\_

If the patient does not understand the question, do not pursue it because you will not get useful information.

Smoking History: TYPE/BRAND \_\_\_\_\_

Number of cigarettes per day \_\_\_\_\_ ÷ 20 = A

Number of years \_\_\_\_\_ = B

Number of pack years \_\_\_\_\_ = A x B

A pack year is a measure of exposure/ risk. Equivalent to smoking a 20-cigarette pack a day for one year. Work this out after taking the case if need be.

Alcohol History: TYPE OF DRINK \_\_\_\_\_

Everyday? YES/ NO



Average number of drinks: cans/bottles/cartons beer\_\_\_\_\_

: bottle wine\_\_\_\_\_

: bottles spirits\_\_\_\_\_

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> <table border="1"><tr><td></td></tr><tr><td></td></tr><tr><td></td></tr></table>				<b>FATHER</b> <table border="1"><tr><td></td></tr><tr><td></td></tr><tr><td></td></tr></table>			
<b>MOTHER'S MOTHER</b> <table border="1"><tr><td></td></tr><tr><td></td></tr><tr><td></td></tr></table>				<b>FATHER'S MOTHER</b> <table border="1"><tr><td></td></tr><tr><td></td></tr><tr><td></td></tr></table>			
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<b>SIBLINGS</b> <table border="1"><tr><td></td></tr></table>		<table border="1"><tr><td></td></tr></table>					

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

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

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


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.


MENSTRUATION: Duration of overall cycle and regularity, duration of menses, volume, colour, consistency, pain, concomitants (e.g. headaches, constipation, diarrhoea 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?


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


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.


CHEST: Problems with breast, breathing, cardiac.


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.


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


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


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


GENERAL: Energy, weather preferences.


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 you characteristics? / What is your personality? Anxiety / worries, anger, sadness/ depression. Relationships. What makes you happy?


Appendix M: Physical examination form/ SOAPE note – case summary



Physical Examination Form/ SOAPE Note – Case Summary

PATIENT DETAILS

DATE:    /    / 2016	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)

ICD-10 CODE:	Written Diagnosis:
--------------	--------------------

## CENTRE OF THE CASE

1.	3.
2.	4.

## CASE ANALYSIS

MENTALS	GENERALS	PARTICULARS

## RUBRICS [3]




## P REMEDY DIFFERENTIALS

1.	4.
2.	5.
3.	6.

## PRESCRIPTION

1.	2.	3.	4.
Rx:	Rx:	Rx:	Rx:
Mitte:	Mitte:	Mitte:	Mitte:
Sig:	Sig:	Sig:	Sig:

## E PATIENT EDUCATION/ADVICE

1.
2.

## SIGNATURES

Clinician's Name:	Student's Name: Behlulile Sukati	Dispenser's name:
Clinician's Signature:	Student's Signature	Dispenser's Signature:
Date:	Date:	Date:

## Appendix N: How to take homoeopathic treatment



### How to take Homoeopathic treatment.

Treatment will be dispensed in a 50ml amber screw top bottle.

Participants will be required to take the treatment at least ½ hour before a meal OR ½ an hour after a meal.

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.

Open the bottle and take medication as instructed on the label.

The dosage is 20 drops in little water TWICE daily. Avoid eating mint, or using camphor (eg. Vicks) while on treatment.

Store the treatment away from heat, light and electromagnetic radiation (e.g. T.V., computers and cellphones)

If drinking coffee, try to wait ½ hour after taking the treatment, before having any.

Always take the treatment as instructed/ directed.

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

Miss. Behlulile Sukati – Researcher: 0736623843

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))

Appendix O: Follow up consultation form



Follow up consultation form

DATE: / /2016

MAIN COMPLAINT(S):


NEW SYMPTOMS THAT HAVE APPEARED SINCE THE REMEDY



Is this an old symptom that has reappeared or is it a new symptom altogether?


If it is an old symptom, when did it start, is it as bad as before, or not, and is it affecting the patient adversely?


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 P: 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 Kessker

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>



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

#### Disclaimer

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## Appendix Q: Permission from gate keepers



### Permission from gate keepers

Cornelia Maria Hall <corneh@dut.ac.za>

5/23/16

to me

Dear Behlulile

Please note that this email serves as proof of permission from the Department of Homoeopathy that you can go ahead and use the clinic facilities for the purpose of conducting your research.

Kind regards

Dr. Hall

MEMORANDUM

To : Prof Ross  
Chair : RHDC  
  
Prof Adam  
Chair : IREC

From : Dr Charmaine Korporaal  
Clinic Director : FOHS Clinic

Date : 21.05.2016

Re : Request for permission to use the Homoeopathic Day Clinic for research purposes

---

Permission is hereby granted to :

**Ms Behlulile Nonsikelelo Stoppy Sukati (student number 20707749),**

**Research title :** "The efficacy of a Homoeopathic mother tincture complex (*Vitex agnus castus*, *Melissa officinalis* and *Valeriana officinalis*) in the management of Premenstrual Dysphoric Disorder."

It is requested that Ms Sukati submit a copy of her RHDC / IREC approved proposal to the Clinic Student Administrator (Mrs Twiggs) before she starts with her research in order that any special procedures with regards to her research can be implemented prior to the commencement of data capture.

Thank you for your time.

Kind regards



Dr Charmaine Korporaal

Clinic Director : FOHS Clinic

Cc: Dr Nienaber : Clinic Co-ordinator  
Mrs Twiggs : Clinic student administrator  
Dr. Jabulile C. Ngobese-Ngubane : Research supervisor  
Dr. Ingrid Couchman : Researcher co-supervisor

## Appendix R: Editing certificate

**Rookmoney Thakur**

Btech: Journalism, M.Phil: Quality Management  
**Ph.D candidate** (DUT)

92 Victoria Road  
Hillary/Durban 4094  
031-464 5041/078-544 2461

Email: maleni.thakur@gmail.com

### LETTER TO SUPERVISOR AND QUOTATION

Date: 25 January 2018

**For:** Ms Behlulile Nonsikelelo Stoppy Sukati (20707749)

**Re:** Proof -reading and editing of M. Tech: Hon dissertation.

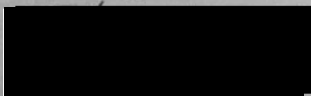
I proof-read, language edit, reference edit, layout edit and meaning edit i.e. change wording to sharpen and/or clarify the meaning of sentences as appropriate. I am presently pursuing a doctorate degree at the Durban University of Technology (D.Phil.: Peace Studies). My first degree, which I obtained at DUT, was a Nat.Dip: Journalism (1995). I obtained a B.Tech: Journalism (2011). I went on to complete an M.Phil. Quality Management (2016). I was employed as a writing tutor at DUT (M.L Sultan Campus) for the year 2015.

My rate is calculated per received page (12 pt. font; 1.5-line spacing) including the front pages but excluding appendixes and is R20 per page, including the List of References.

Quotation for the services rendered to Ms Sukati is **R1 880.00** (94 pages @ R20).

Should you have any enquiries please feel free to contact me.

Best Regards



Mrs. R. Thakur



