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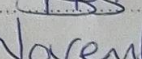
Sign: 

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Premenstrual Dysphoric Disorder: prevalence, symptomatology and coping practices amongst women attending Tertiary Educational Institutions in Machakos Subcounty, Kenya

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A Research in partial fulfilment for the degree of Master of Medicine (Psychiatry)

Supervisors:

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DECLARATION OF ORIGINALITY

I, Dr Stanley Nzau Muange, do hereby declare that this is my original work carried out independently in fulfillment of the requirements for the award of the degree of Master of Medicine (Psychiatry), Department of Psychiatry, the University of Nairobi. I further declare that this work has not been presented for the award of any other degree or to any other University.

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LIST OF ABBREVIATIONS AND ACRONYMS

APA: American Psychiatric Association

CIDI: Composite International Diagnostic Interview

Copper IUD: Copper coated Intra-uterine Device

DRSP: Daily Record of Severity of Problems

DRSS: Day Rating of Severity of Symptoms

DSM: Diagnostic and Statistical Manual

DSM IV– TR: Diagnostic and Statistical Manual 4th Edition Text Revision

DSM-5: Diagnostic and Statistical Manual 5th Edition

DSM-IV: Diagnostic and Statistical Manual 4th Edition

GABA: Gamma Amino Butyric Acid

GnRH: Gonadotropin Releasing Hormone

IUD: Internet Use Disorder

KNBS: Kenya National Bureau of Statistics

MCRH: Machakos County Referral Hospital

MINI: Mini International Neuropsychiatry Interview

PMDD: Premenstrual Dysphoric Disorder

SPAF: Shortened Premenstrual Assessment Form

SSRI: Selective Serotonin Re-uptake Inhibitors

OPERATIONAL DEFINITIONS

1. Tertiary Educational Institution means any post-secondary school or institute of learning
2. Menses refers to the menstrual period
3. Study or research means any academic investigative work undertaken to further knowledge
4. Early Reproductive years is 18 to 35 years

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ABSTRACT

Background
Premenstrual Dysphoric Disorder (PMDD), is a severe gender-specific mood disorder characterized by cognitive, affective and physical symptoms in the week before onset of menses, with compete symptom remission after the menses. The global prevalence of Premenstrual Dysphoric Disorder (PMDD) has been estimated at 5% although studies done in a number of countries place the prevalence at a range between 3 and 37%. There is paucity of data regarding this disorder in the African context, and the researcher found only four published African studies, done in Ethiopia and Nigeria, reporting a prevalence range of 6.1 to 36.1%. No published Kenyan study on PMDD was found.

Study Objectives
This study aimed at establishing the prevalence, symptomatology and coping practices regarding PMDD amongst women attending tertiary educational institutions in Machakos subcounty. Towards this end, the study specifically determined the prevalence of PMDD in women attending tertiary institutions in Machakos subcounty, identified common symptoms expressed by women with PMDD and found out what coping strategies are practiced by women with PMDD in Machakos subcounty.

Methodology
Data was collected from students attending the four major tertiary educational institutions with a national catchment within Machakos subcounty. Participants were drawn randomly from each one of the institutions through simple random sampling method to make up a sample of 351 women. Self-administered Questionnaires were used as data-collection tools for this study. The data collected was analyzed with SPSS version 25.0

Study Findings
The study found PMDD prevalence rate of 31.3%, and an association between PMDD and Dysmenorrhoea. It was also established that most women with PMDD have physical symptoms in addition to affective ones. Further, it was found that majority of women with PMDD resort to over-the-counter painkillers rather than seeking medical help

Discussion of Findings
Similar studies done in various countries tend to show a variable prevalence rate of PMDD, possibly due to differences in methodology. Developed countries have a lower PMDD prevalence compared to developing ones. Generally, cross sectional studies tend to give higher rates. In addition, the intensity and expressivity of PMDD symptoms may be related to sociocultural background, family perspectives, religious beliefs, social tolerance and gender roles. The most accurate determination of prevalence rate should be Daily Rating of Severity of Symptoms, a prospective study

Conclusions and Recommendations
This study concluded that prevalence of provisional PMDD was 31%, with an association between PMDD and Dysmenorrhoea. There was no association between PMDD and age at menarche, contraceptive use nor regularity of menstrual cycle. Emotional lability, depressive symptoms and physical symptoms were commonly expressed by women with PMDD. Painkiller use was very prevalent in women with PMDD and medical attention was rarely sought. The study recommends further research in Kenya to accurately determine the prevalence rate of PMDD using a prospective design. Also needed is a study on knowledge, attitudes and practices of health providers regarding PMDD to provide baseline data in preparation for the much-needed training on diagnosis and management of PMDD. Finally, there is need for sensitization of community members on PMDD and the available medical interventions

CHAPTER ONE: INTRODUCTION

1.1 Background Information

The global prevalence of Premenstrual Dysphoric Disorder (PMDD) has been estimated at 5% (Sepede et al 2016). This makes it one of the most significant but least addressed gender-specific mental disorders globally, cloaked in the same silence and mystery that surrounds female menstruation. Compounding the general neglect of the disorder by the society is the equally unexplained neglect by the health systems. It is worth noting that inclusion of PMDD in the Diagnostic and Statistical Manual (DSM) as a full diagnostic category is a relatively recent event. In the DSM IV– TR edition, PMDD was listed, but not as a full diagnostic category. Endicott, et al, in 1999, contrasted symptomatology of PMDD and other mood and anxiety disorders, where it was found that PMDD had clear cluster of clinical features closely linked to the menstrual cycle and the eminence of symptoms of anger, irritability, and internal tension**.** Further, it was clear that PMDD displayed a definite clinical presentation that, in the absence of intervention, was remarkably unchanging from one month to the next, throughout. It was only in 2012 that a working-group of global professionals on the pathobiology and management of PMDD tendered to the APA DSM-5 Executive Committee an overview of the prevailing science about PMDD. This committee of experts, after a thorough consideration of the available scientific data, recommended that PMDD be included in the DSM-5 as a stand-alone diagnostic class (Epperson et al, 2012)

The aetiology, pathogenesis and indeed the neurobiology of PMDD are not yet clear (Protopopescu et al, 2008; Bixo et al, 2018). A biopsychosocial model was proposed by Hantsoo et al (2015). According to this model, available evidence implicates women's unique response to cyclical hormonal changes, especially the neuroactive oestrogen and progesterone in a

genetically predisposed individual within an environment of psychosocial factors. Recent experimental evidence suggests that although the aetiology of PMDD is unknown, a relationship between circulating ovarian steroids (notably progesterone and its metabolite Allopregnanolone) and PMDD has been established during luteal phase. This has been found to be operating through the $GABA_A$ Receptor (Bixo et al 2018).

Smith et al (2006) found that Progesterone and its metabolite Allopregnanolone get elevated in the second half of menstrual cycle but decline acutely around onset of menses, possibly becoming key to onset of PMDD. Later, Li et al (2012), designed a Rodent-model to test effect of Progesterone withdrawal and found that this was associated with anhedonia and social withdrawal. In 2009, Schneider et al, had reported that chronic exposure to Progesterone succeeded by sudden cessation was related to enhanced anxiety behavior and variations in γ-aminobutyric acid (GABA) receptor functioning, possibly linking GABA function to the depression symptoms. This involvement of the GABAergic system has also been shown using proton magnetic resonance spectroscopy by Liu et al (2015). Allopregnanolone has been proven to be a potent GABA receptor modifier same as alcohol and benzodiazepines, causing anxiolysis, sedation and having anaesthetic properties (Schüle et al, 2014). Thus, the pathogenesis of PMDD is linked more to this metabolite rather than the parent hormone Progesterone (Bäckström 2011). In fact, low levels of Pregnanolone within specific areas of the brain like Amygdala, Hippocampus and Medial Prefrontal Cortex have been demonstrated in animal models with anxiety and depressive symptoms (Nelson et al, 2011). Allopregnanolone promotes GABAergic function, providing sedation in periods of stress, hence maintaining homeostasis. Studies have shown that Allopregnanolone levels increase in response to acute stress (Crowley et al, 2014) and that patients with PMDD do not exhibit this characteristic and protective Allopregnanolone

increase (Girdler et al, 2001). This was corroborated in a study which showed that giving exogenic Allopregnanolone reverses longterm depression and anxiety-like behaviors subsequent to stress and restitutes Hypothalamus-Pituitary-Axis function (Evans et al, 2012). Furthermore, a study involving nearly 4000 American women found that trauma history and PTSD were independently associated with PMDD diagnosis (Pilver et al, 2011)

Oestradiol has also been identified as another possible culprit in the pathogenesis of PMDD, exerting its effect on a number of neuronal pathways for the modulation of mood, cognition, sleep, eating, and other aspects of behavior (Shanmugan et al, 2014; Kugaya et al 2003; Fink, et al, 1998; Rehavi et al, 1998). In 2015 Hantsoo, et al, proposed that females suffering from PMDD are highly responsive to oestrogens on brain pathways utilizing serotonin. Indeed, females suffering from PMDD show low moods, predilection to certain foods, and abnormal cognition during the second half of their menstrual cycle. All these affective and cognitive features may be affected by serotonin.

Genetic predisposition has been found to play a role in genesis of PMDD. Single Nucleotide polymorphisms of the *ESR1* as well as the 5-HT gene have both been associated with PMDD. However most of the genetic studies used small sample-sizes and further research in this area is needed (Hantsoo et al, 2015).

Other studies have also associated PMDD with increased pro-inflammatory activity (O'Brien et al, 2007; Northoff et al, 2008) and one researcher actually found increased inflammatory markers in women with PMDD (Bertone-Johnson et al, 2014)

According to Hantsoo, et al (2015), a clinical definition of PMDD relies mainly on symptomatology. In both latter DSM Editions (DSM-IV and DSM-5) categorization of PMDD is

reliant upon a cluster of at least five symptoms (physical, affective, and/or behavioral), whereby at least one of them being the cardinal affective symptoms of affective lability (mood swings, tearfulness, sensitivity to rejection); irritability or anger that is often characterized by increased interpersonal conflicts; marked depressed mood, hopelessness, or self-deprecating thoughts; or anxiety, tension or feeling on edge. In addition, the patient may experience difficulty concentrating, a sense of feeling overwhelmed, behavioral and somatic symptoms such as loss of interest in usual activities, lack of energy, changes in appetite or food cravings as well as changes in sleep patterns. Physical features particularly occurring prior to menses such as breast tenderness, breast swelling or bloating are also experienced. DSM-5 lists mood lability and irritability as symptoms, for the first time, based on studies done, which found that these features are considerably more prevalent in females with PMDD than low mood which had been prioritized earlier in the DSM-IV (Hantsoo et al, 2015)

1.2 Problem Statement

Premenstrual Dysphoric Disorder is a gender-specific condition with an average global prevalence of 5% (Sepede et al 2016). PMDD affects the health of the individual woman as well as her functioning at the workplace and society (Issa et al), interferes with both the work as well as social functioning of the affected (APA, 2013), causes significant morbidity in adolescents and is prevalent across cultures (Ogebe et al, 2011). Pilver et al, (2013) found a directly proportional increase of non-fatal suicidal prevalence and PMDD status. This disorder is also a potential cause of interpersonal conflict, and may be implicated in many cases of family and workplace strife (Hantsoo et al, 2015; Mahfoud et al, 2018). Ultimately, PMDD burdens the healthcare systems as described by Sepede et al (2016), who asserted that women with PMDD have increased use of health care services such as clinician visits and increased use of

prescription medications and over-the-counter preparations. Studies on PMDD have been done in a number of countries, where the prevalence was found to range between 3 – 37%. Workers in the USA report a varied prevalence of PMDD, ranging from 3 - 18% (Halbreich et al, 2003; Rapkin et al, 2011; Bixo et al, 2018), Similar studies in Switzerland placed the prevalence at 3.1% (Tschudin et al, 2010). In Brazil, the prevalence of PMDD was found to be 17.6% (De Carvalho et al, 2018) while in Qatar it was found to be 3 - 9% (Mahfoud et al, 2018). One study in the Indian subcontinent placed the prevalence there to be 37% (Mishra et al, 2015). In Africa, there is paucity of data on PMDD, with only four studies on the disorder found. Adewuya et al (2008) found a prevalence of 6.1% in students of a Nigerian university, and concluded that this rate indicated that PMDD prevalence in sub-Saharan women was similar to other parts of the world. A more recent study done by Jember et al, in 2017 found a prevalence of 26.8% in a sample of 520 female students. No Kenyan studies on PMDD were found.

From the foregoing therefore, it's doubtless that PMDD is largely an unseen and little recognized problem affecting a significant number of women in their reproductive years, subsequently adversely affecting their socio-occupational functioning and productive capacity. To confound this dire situation is the gross paucity of data on PMDD in the local context making it a real challenge to mitigate its morbidity

CHAPTER TWO: LITERATURE REVIEW

2.1 Prevalence of PMDD

The prevalence of PMDD varies amongst different researches. Halbreich et al (2003), while assessing available published reports, gave early estimates of the prevalence of PMDD at 13-18% in terms of clinically significant disease without necessarily satisfying the criteria of minimum of 5 symptoms. However at the time of the study, the prevalence was estimated at 3 – 8%. Tschudin et al, (2010), in a Swiss Health Survey involving 3,913 women aged 15 – 54 years, found a prevalence of 3.1%. This figure was somewhat similar to another by Rapkin et al (2011) in an overview of the prevailing information at the time, who reported a prevalence of 3-8%. Sepede et al (2016), who searched a total of 55 PubMed studies on PMDD, gave prevalence of 2 - 8% whereas Wittchen et al (2002), doing a prospective longitudinal community survey on PMDD in a sample of 1488 women between 14 and 24 years in Germany, found a prevalence of 5.3%.

Recent studies have also given conflicting prevalence reports. Bixo, et al (2018), while investigating the effects of GABA-active steroids on the female brain using a controlled trial, stated a prevalence of 3 - 5%. De Carvalho et al (2018), doing a community survey using a sample of 727 women aged 18 to 24 years in Brazil, found a higher prevalence of 17.6%. Mahfoud et al (2018), during a study in Qatar to validate an Arabic version of the Premenstrual Screening Tool where a total of 194 women were respondents, found a prevalence of 15%. Mishra et al (2015), reporting about the situation in India, found a high prevalence of 37%. He did a study on 179 medical students to find out the association of socio-demographics and lifestyle with PMDD. Closer home, the situation has been equally variant. In an Ethiopian study, the figure was reported to be similarly high at 26.8% (Jember et al, 2017).

One possible explanation to this apparent discrepancy in prevalence of PMDD could be the assertion by one researcher, Mishra, et al (2015), who found that cultural factors may influence symptom expression, in agreement with DSM 5 statement that the intensity and expressivity of PMDD symptoms may be related to sociocultural background, family perspectives, religious beliefs, social tolerance and gender roles (APA, 2013). In addition, use of different methods and tools by different workers does affect reliability of the results

2.2 Literature on Methods and Tools

Various research approaches and methods have been employed to study PMDD. Preclinical research using animal models has been key in providing information on the possible aetiology, pathogenesis, and treatment of PMDD. In 2009, Schneider, et al, developed an animal model for studying the role of antidepressants in PMDD. He demonstrated that long-term exposure to progesterone followed by prompt cessation is related to high anxiety behaviors. Further work by Li, et al, (2012), linked social withdrawal and anhedonia to cessation of progesterone dosing. Neuroimaging techniques have also been used to study PMDD. An example in this area is the work of Rapkin et al (2011), who used this approach to study Cerebellar involvement in PMDD.

Most clinical research into PMDD was accomplished using the criteria provided in DSM-IV and DSM 5 (Wittchen et al 2002; Mishra et al 2015). Way back in 2002, one researcher lamented that consistent data on prevalence of PMDD in general population was lacking (Cohen et al, 2002). Since then, substantial work has been done using Retrospective longitudinal studies, Cross-sectional, as well as Prospective studies. Wittchen et al (2002), did a prospective longitudinal community survey 1488 women aged 14-24 years, following them up in a period of 48 months, where the prevalence of PMDD was found to be 5.8%. A similar approach was employed by Cohen et al (2002), where they did a prospective evaluation using Day Rating of

Severity of Problems in a sample of 513 women. This study found the prevalence of PMDD to be 6.4%. Quite a number of cross-sectional studies have been reported. Mishra, et al (2015), Jember et al (2017) and De Carvalho et al (2018) used cross-sectional studies in PMDD research, reporting prevalence of 37%, 26.8% and 17.6% respectively. An example of a meta-analysis study is what is reported by Sepede et al (2016) where a review of 55 previous studies on PMDD was done, and the prevalence of PMDD ranged between 2 – 8%. Cross-sectional studies are easier to do and less costly but for more reliable and valid results longitudinal studies are preferable in PMDD due to the cyclic nature of the disorder.

Globally, there has been no agreement on a single tool for the study of PMDD in populations. Quite a number of tools have been used over the years for various objectives and with a variety of outcomes. In 1991 Allen, et al, reported use of the Shortened Premenstrual Assessment Form (SPAF. Other workers, writing 11 years later, reported having used SPAF too (Feurstein et al, 2002). More recently, Mishra et al, (2015) translated and used SPAF in an Arabic population at Doha in Qatar with good results.

Other tools that have been used successfully include: Day Rating of Severity of Symptoms (DRSS) by Cohen et al (2002), prevalence 6.4% ; Composite International Diagnostic Interview (CIDI) by Wittchen et al (2002), prevalence 5.8%; and Mini International Neuropsychiatry Interview (MINI) by Carvalho et al (2018), prevalence 17.6%.

2.3 Literature on Symptomatology of PMDD

The debate on what exactly constitutes PMDD symptoms has been vigorous, eventually settling down to two categories, physical symptoms and emotional, with resultant functional impairment that lies on the severe end of the continuum of premenstrual symptoms (Lanza di Scalea, 2017). Publication of DSM-IV and its successor DSM 5 made clinical diagnosis more reliable by

outlining specific criteria. In both recent DSM Editions (DSM-IV and DSM-5) categorization of PMDD is reliant upon a cluster of at least five symptoms (physical, affective, and/or behavioral), whereby at least one of them being the cardinal affective symptoms of affective lability (mood swings, tearfulness, sensitivity to rejection); irritability or anger that is often characterized by increased interpersonal conflicts; marked depressed mood, hopelessness, or self-deprecating thoughts; or anxiety, tension or feeling on edge. A major difference between DSM-IV and DSM 5 symptomatology of PMDD is that while DSM-IV gave prominence to depressed mood, DSM 5 prioritized mood lability and irritability (APA, 2000; 2013).

Delineating PMDD as an entity within the Mood and Anxiety disorders family was actualized in DSM 5 through a committee recommendation (Epperson et al, 2013). However, even as early as 1999 a distinction was already apparent. Endicott et al (1999) contrasted PMDD with known mood and anxiety disorders and found that PMDD shows a unique clinical symptomatology that, without medical intervention, is amazingly unchanging each and every menstrual cycle

Mahfoud et al (2018) clarifies that clinical Features of PMDD fall into three classes (See Table 2.1)

Table 2.1: Classes of PMDD Symptomatology

CLASS OF PMDD SYMPTOMS	**PRESENTATION**
MOOD SYMPTOMS	Anxiety, Depression, Irritability, Anger, Affective Lability(mood swings, tearfulness, sensitivity to rejection), Hopelessness, Self-deprecating thoughts, Tension, Feeling on Edge

PHYSICAL SYMPTOMS	Abdominal Bloating, Joint or Muscle Pains, Breast tenderness or swelling, Headache, Weight Gain
OTHER SYMPTOMS	Poor Concentration, Decreased Interest in daily activities, Lethargy, Fatigue, Changed Sleep Patterns, Changed Appetite

Source: modified from Mahfou, et al (2018)

Further, according to Mahfoud et al (2018), the features need to be there in several menstrual cycles, start in the week prior to onset of the period, and regress and remit after the onset of the period. Indeed, to be considered diagnostic, these features need to cause notable negative effect or impairment in work, social, or interpersonal functioning.

DSM 5 (APA, 2013) gives specific guidelines on the use of PMDD symptomatology. The history given by the patient can be used to reach a diagnosis of PMDD, following the criteria outlined. However, this diagnosis must be labelled "Provisional" until a prospective Daily Rating of Severity of Symptoms (DRSS) is done for at least two consecutive menstrual cycles.

2.4 Literature on Treatment Strategies for PMDD

As far back as 20 years ago, selective serotonin reuptake inhibitors (SSRI) were identified as first line treatment for PMDD. According to one study, up to 60% of women responded well to this class of drugs when given low doses intermittently. Sani et al (2014), observed that available treatments of PMDD were unsatisfactory as many women were not responding to conventional drugs. Sepede et al (2016), reported that Selective Serotonin Reuptake Inhibitors (SSRI) were the best option for the treatment of PMDD in the absence of other mental disorders. The same study also recommended use of low doses of Oestroprogestins, and concluded that efficacy of Light

Therapy, Behaviour Therapy, Food supplements and Herbal Medicine, though promising, needed more research. Use of SSRI as first-line treatment of PMDD is also recommended by Gabbard (2016) in a continuous, intermittent or dose-adjusted phasic regimen.

One of the most up to date and comprehensive write-ups on PMDD treatment is by Eisenlohr-Moul (2019). In this work, PMDD treatment options are divided into: Treatments with strong scientific evidence for efficacy and safety in PMDD, Treatments with limited but promising scientific evidence for efficacy and safety in PMDD and Treatments with no evidence, mixed evidence, or negative evidence for efficacy in PMDD (See Table 2.2 below)

Table 2.2: Treatment Options in PMDD

PMDD TREATMENT OPTION	**EXAMPLES**
Treatments with strong scientific evidence for efficacy and safety	SSRI, Drospirenone-containing oral Contraceptives, Gonadotropin Releasing Hormone (GnRH) analogues, GnRH analogues + Stable Hormone Addback, Total hysterectomy with bilateral salpingo-oophorectomy, Cognitive-Behavioral Therapies
Treatments with limited but promising scientific evidence for efficacy and safety	5-alpha Reductase Inhibitors, Ovulation suppression using Transdermal Estradiol + cyclical Progestogen, Quetiapine (luteal phase; adjunct to SSRI), Isoallopregnanolone injections

Treatments with no evidence, mixed evidence, or negative evidence for efficacy	Lifestyle Changes, Vitamin and Mineral Supplements, Levonorgestrel-containing Continuous Oral Contraceptive, Levonorgestrel-containing Intrauterine Device, Copper IUD, Danazol, Benzodiazepines

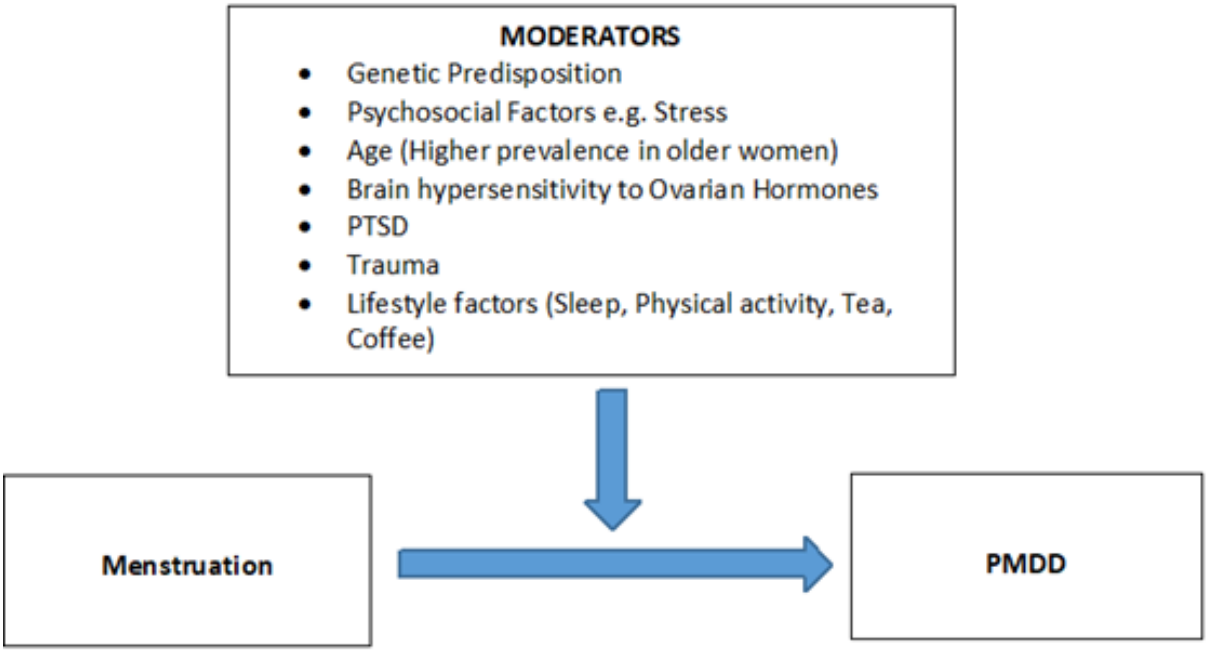
Source: modified from Eisenlohr-Moul (2019)

Women suffering from PMDD often result to self-medication and other strategies in a bid to alleviate their suffering and improve quality of life. One study done in Jordan identified taking analgesics, wearing heavy warm clothes, drinking hot fluids and lying on the abdomen as some of the common such practices (Hamaideh et al, 2013)

2.5 Theoretical Framework

From the available scientific information about PMDD, the factors that can theoretically modify the normal physiological process of menstruation into a disorder are as summarized in the theoretical framework shown below:

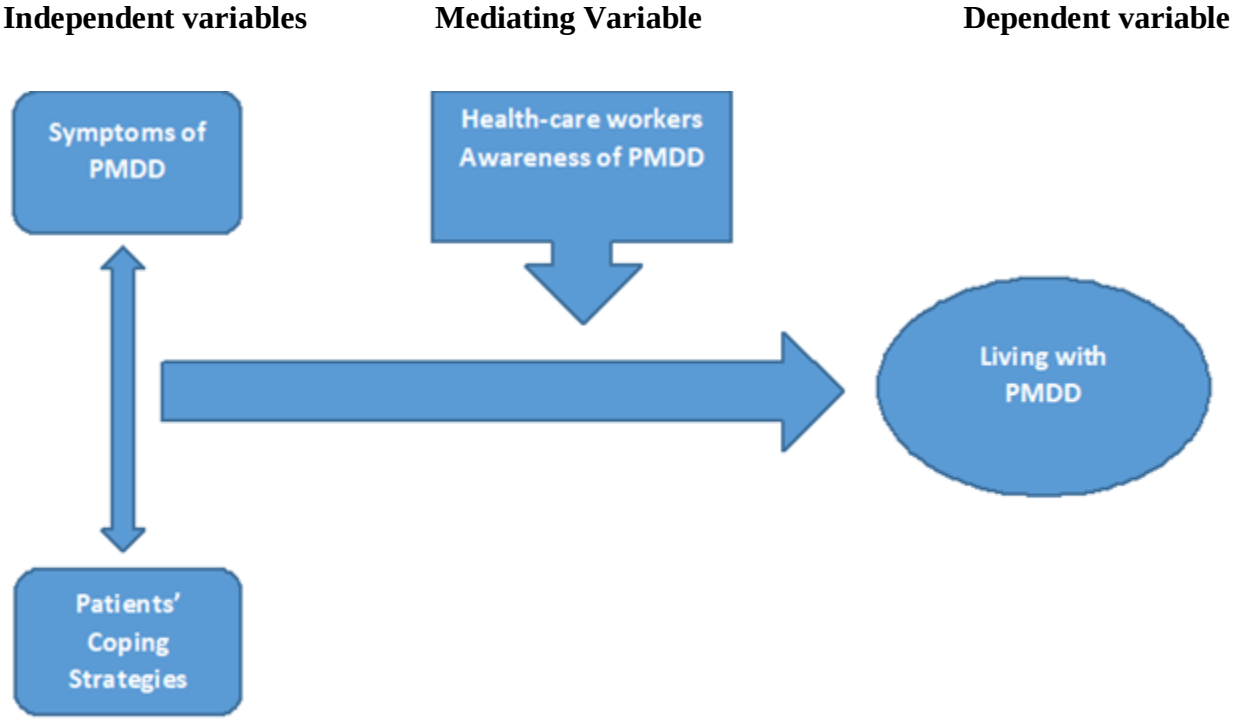
Figure 2.1: Theoretical Framework



2.6 Conceptual Framework

For this study, the conceptual framework is as shown in the figure below:

Figure 2.2: Conceptual Framework



2.6 Justification of the Study

PMDD is a debilitating, yet largely unexplored disease. The neurobiology is poorly understood – its aetiology, pathophysiology and pathology still subject of active research. Even the controversies surrounding its classification as a category in DSM 5 have not yet died down. Very little is known about PMDD in African populations, and virtually nothing in Kenyan women, there being no studies found addressing PMDD. Since the Constitution of Kenya (2010) requires that every Kenyan receive the highest quality of healthcare possible, this study aimed at addressing this knowledge gap, and provide basis for further research in the area of Reproductive Psychiatry in general, and PMDD in particular.

2.7 Research Questions

This study answered the following questions:

a) What is the prevalence of PMDD in women attending tertiary institutions in Machakos subcounty?
b) What are the common symptoms experienced by women with PMDD?
c) What coping strategies are practiced women with PMDD?

2.8 Objectives of the Study

2.8.1 Overall Objective

To establish the prevalence, symptomatology and coping practices regarding PMDD amongst women attending tertiary educational institutions in Machakos subcounty

2.8.2 Specific Objectives

a) To determine the prevalence of PMDD in women attending tertiary educational institutions in Machakos subcounty

b) To identify common symptoms of PMDD experienced by women with the disorder in Machakos subcounty

c) To find out what coping strategies are practiced by women with PMDD in Machakos subcounty

CHAPTER THREE: METHODOLOGY

3.1 Introduction

This chapter describes and presents the approach that was used in the study. It describes the details of the study design and process, population sample and sample size, inclusion and exclusion criteria, data collection instruments which were used to achieve the study objectives, data management and analysis.

3.1 Study design

This study was of a quantitative and qualitative descriptive cross-sectional design

3.2 Background of Study Area

Machakos County is county number 16 in Kenya. Its capital is Machakos Town, which is also its largest town, and Kenya's first colonial administrative headquarters. The county had a population of 1,421,932 as of 2019 (KNBS, 2019). The county borders Nairobi and Kiambu counties to the west, Embu to the north, Kitui to the east, Makueni to the south, Kajiado to the south west, and Muranga and Kirinyaga to the north west.

Machakos County is divided into nine subcounties, namely: Machakos, Athi River, Kathiani, Kalama, Kangundo, Matungulu, Mwala, Yatta, and Masinga.

Machakos subcounty is the most urbanized of the subcounties, and also hosts the county headquarters. This subcounty consists of Machakos Town and outlying suburban areas. The population of Machakos subcounty as per last census was 170,606; of which males were 85,486, females 85,114 and Intersex 6 (KNBS, 2019).

The Major tertiary Educational Institutions within Machakos subcounty include Machakos University, Scott Christian University, South Eastern Kenya University (SEKU), St. Paul's

University, Century Park College, Machakos Institute of Technology, Kenya Medical Training College, Machakos campus, Kenya Medical Training College, Manza Campus, Machakos Teachers College, Machakos Medical and Technical Training College and Machakos Technical Training Institute for the Blind. A number of smaller vocational institutes are also found in the subcounty. Five of these institutions, namely, Machakos University, Scott Christian University, Kenya Medical Training College Machakos campus, Kenya Medical Training College Manza Campus and Machakos Teachers College were chosen as study sites for this research. Their combined student population at the time of the study was 12,891 as shown in table 3.1 below:

Table 3.1: Student Population in Study Sites

INSTITUTION	**MALES**	**FEMALES**	**TOTAL**
Machakos University	6588	3082	9670
KMTC Manza Campus	325	475	800
KMTC Machakos Campus	395	515	910
Scott Christian University	582	490	1072
Machakos Teachers College	167	272	439
TOTALS	**8057**	**4834**	**12891**

3.3 Study Population

The study population was all women within early reproductive years (18 – 35 years) in most parts of rural Kenya. Target population was women in early reproductive years attending Tertiary Educational Institutions in Machakos Subcounty. The selected participating institutions had a combined female population of 4,834 distributed as shown in Table 3.1 above.

3.4 Sample Size

The sample size of women for this study was based on the formula suggested by Charan and Biswas (2013) for use in calculating sample size in medical research. Using this formula, sample size (n) was determined thus:

$n = Z^2P(1-P)/d^2$

where:

Z is the standard normal variate or confidence interval. If a confidence interval of 95% is adopted (p = 0.5), Z is 1.96; P is the proportion of population with the characteristic under study (using the results of an Ethiopian study (Jember, et al, 2017), this proportion is 0.268); d is the absolute error, in this study estimated at 5% (0.05)

Applying the formula, a sample size of 301 women is calculated, as shown:

$n = 1.96^2 \times 0.268 \times 0.732 / 0.05^2 = 301.45$

3.5 Sampling Procedure

Stratified Sampling was used to obtain a sample of women respondents from the major tertiary educational institutions in the subcounty. First, five tertiary institutions were purposively selected based on their nationwide catchment. Using this criterion, the selected institutions proposed were: Machakos University, Scott Christian University, Machakos Teacher Training College, Kenya Medical Training College, Machakos campus and Kenya Medical Training College, Manza campus. Next, a proportionate sample was drawn from each institution based on the female student population in the respective institution, to make up the sample size (see Table 3.2 below):

Table 3.2: Proportionate sample of Respondents based on female students per institution

INSTITUTION	TOTAL FEMALES	PROPOSED QUOTA	ACTUAL PARTICIPANTS
Machakos University	3082	191	217
KMTC Manza Campus	475	30	41
KMTC Machakos Campus	515	32	63
Scott Christian University	490	31	30
Machakos TT College	272	17	0
TOTALS	**4834**	**301**	**351**

As can be seen above, one of the institutions, Machakos Teachers College did not have students at the time of the study and therefore did not participate. In addition, the response in the participating institutions was quite vibrant and the respondents exceeded the minimum number calculated.

3.6 Recruitment Procedure

Female students aged between 18-35 years of age attending the major tertiary educational institutions within Machakos subcounty were randomly recruited into the study, to make up a sample of 351. The Lead Researcher used simple random method using the Enrollment Registers in each institution to select participants, broadly guided by the Quota described in Table 3.2 above. Each participant selected was given the consent explanation form to read. Once the researcher was satisfied that the respondent had understood the contents of the said form, he offered the consent form for signing. After that the respondent proceeded to fill in the

questionnaire. Thereafter the Questionnaires were collected, checked for completeness, serialized and stored safely

3.7 Inclusion criteria

All females aged between 18 and 35 years of age attending the four selected major tertiary educational institutions in Machakos Subcounty of Machakos County, Kenya

3.8 Exclusion Criteria

This study excluded any woman who declined to give consent, or was outside the age bracket of 18 – 35 years, or was not a student in the four selected institutions

3.9 Data Collection Tools

This study used a specially-designed self-administered questionnaire for data collection. The questionnaire had two sections: a Socio-demography section and a section on PMDD information (see Appendix 2).

3.10 Data Collection Procedure

Data for this study was collected solely by the researcher using a tool designed specifically for this purpose. The questionnaire was based on the symptomatology of PMDD given in DSM 5, and validated by use in other similar studies. The Lead Investigator visited each of the four major tertiary educational institutions and using the institutions' registers, randomly selected female students to fill the questionnaire, as per the distribution proposed in the Table 3.2 above.

3.11 Pretesting of Tools

The data collection tool was pretested on female students in Machakos Medical and Technical Training College, which was not participating in the main study. A formal request in writing was made to the Institution's Director and approval obtained. The researcher was allocated 10 female

students who filled the Questionnaire after understanding that this was a pretest exercise, and giving due consent. The average time of filling the Questionnaire was noted to be 10 minutes, and no major difficulties were observed.

3.12 Data Processing, Analysis and Dissemination of Results

All filled questionnaires were verified as complete, serialized and securely stored by the Lead researcher. The data collected in this study was cleaned, coded and summarized in Excel sheet before being analyzed with SPSS version 25.0. The prevalence of PMDD was determined based on the DSM-5 criteria on diagnosis of PMDD and presented in numerical value. The symptoms expressed by the respondents were identified by the Lead Researcher and chunked into clusters. Respondents also gave information on the specific practices they undertake to mitigate the distress of the symptoms of PMDD, and these were also chunked into clusters. The information regarding symptom expression and coping strategies was of nominal qualitative nature and was presented in bar-graphs, tables and narrative. The Lead Investigator made recommendations based on the conclusions and compiled a full report, presented to the Department of Psychiatry in the College of Health Sciences of the University of Nairobi. Thereafter, the findings, conclusions and recommendations of this research will be disseminated through the Department of Health and Emergency Services of the Government of Machakos County to the relevant policy-makers for appropriate action, as well as all the participating institutions.

3.13 Ethical Considerations

All processes in this study strictly adhered to and followed the KNH-UoN ERC Protocols. The study proposal was presented to the Department of Psychiatry of the UoN, and thereafter forwarded to the KNH-UoN ERC for purpose of obtaining a Research Permit. Approval by KNH-UoN ERC was given after the recommended corrections, and a Research Licence sought from

NACOSTI. Once the researcher got the NACOSTI Licence, participating institutions were requested in writing to authorize collection of data. The lead investigator, after recruiting the requisite number of participants in each institution with the authority of the head of the institution, provided each respondent with a copy of the Consent Explanation Form and ensured the same is read and understood. The consent explanation form included an explanation of the purpose of the research and the expected duration of the participation, a description of the procedures that were to be followed and the risks involved, namely invasion of personal life on questions related to PMDD. Regarding this, it was explained clearly that respondents were only required to provide information, and that no tissue or fluid samples were to be drawn or obtained.

The benefits of the study to the participants were explained in detail i.e. this study will help in understanding PMDD and how best to manage it; as well as identify any respondent requiring medical attention in the course of data collection, for appropriate referral to a competent facility.

Respondents were assured that privacy and confidentiality were be highly maintained throughout the study, and that no identifying information was to appear in the report or subsequent journal articles. Participants were also assured that the information given would always remain private and confidential.

CHAPTER FOUR: STUDY FINDINGS

4.1 Introduction

This chapter describes the findings of the study, broadly, the Sociodemographic characteristics of the respondents, the prevalence of PMDD amongst the study population, the symptomatology of PMDD as expressed by the respondents and the coping practices of those found to have PMDD.

4.2: Socio-demographic characteristics of the study population

Data for this study was collected by the lead researcher between January and March 2021. A total of 351 women participated in this study, against 301 proposed, with a response rate of 116.6%. These women were drawn from four tertiary educational institutions in Machakos Subcounty, Kenya, as summarized in Table 4.1 below. One of the institutions previously selected to participate, Machakos Teachers College, had no students at the time of data collection and therefore had no participants in this study.

Table 4.1: Distribution of respondents by educational institution *(n=351)*

Institution	**Expected No. as per Proposal**	**Actual No. that participated**	**%**
Machakos University	191	217	62.0
Scott Christian University	31	30	8.6
KMTC Machakos Campus	32	63	17.7
KMTC Manza Campus	30	41	11.7
Machakos Teachers College	17	0	0
TOTAL	**301**	**351**	**100**

The distribution of respondents by Home-County is shown in Table 4.2

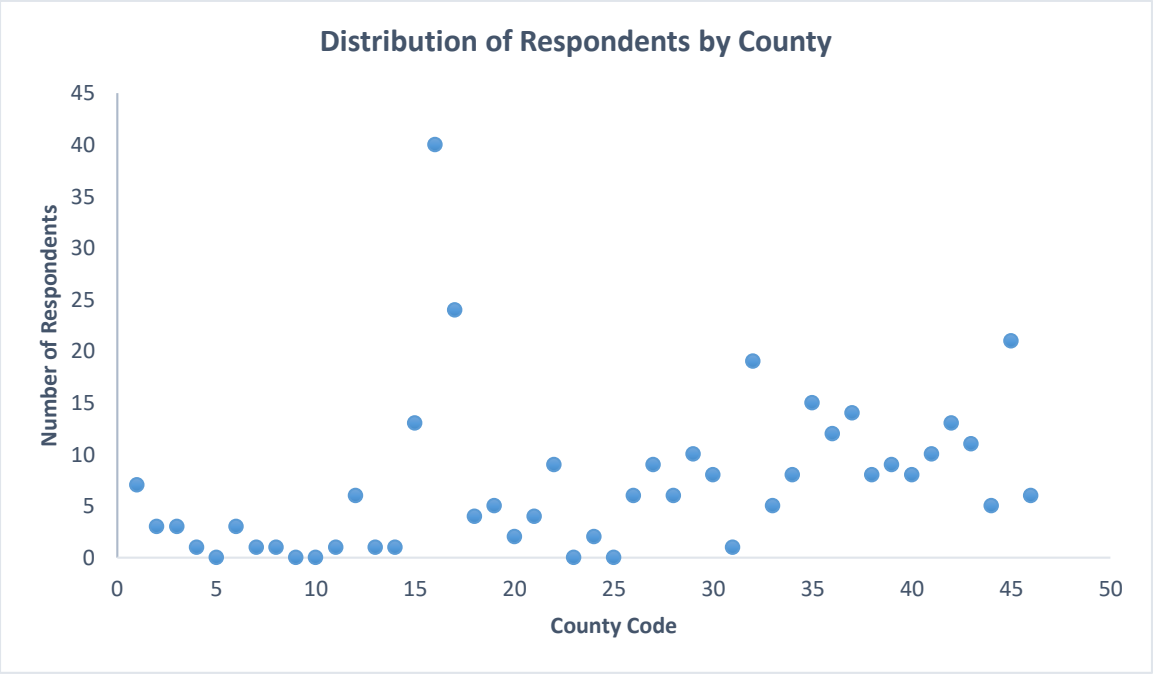
Table 4.2: Distribution of respondents by Home County *(n=347)*

County Code	County	Number (%)
01	Mombasa	7 (2.0)
02	Kwale	3 (0.9)
03	Kilifi	3 (0.9)

04	Tana-River	1 (0.3)
05	Lamu	0 (0)
06	Taita/Taveta	3 (0.9)
07	Garissa	1 (0.3)
08	Wajir	1 (0.3)
09	Mandera	0 (0)
10	Marsabit	0 (0)
11	Isiolo	1 (0.3)
12	Meru	6 (1.7)
13	Tharaka-Nithi	1 (0.3)
14	Embu	1 (0.3)
15	Kitui	13 (3.7)
16	Machakos	40 (11.5)
17	Makueni	24 (6.9)
18	Nyandarua	4 (1.2)
19	Nyeri	5 (1.4)
20	Kirinyaga	2 (0.6)
21	Murang'a	4 (1.2)
22	Kiambu	9 (2.6)
23	Turkana	0 (0)
24	West Pokot	2 (0.6)
25	Samburu	0 (0)
26	Trans Nzoia	6 (1.7)
27	Uasin Gishu	9 (2.6)
28	Elgeyo/Marakwet	6 (1.7)
29	Nandi	10 (2.9)
30	Baringo	8 (2.3)
31	Laikipia	1 (0.3)
32	Nakuru	19 (5.5)
33	Narok	5 (1.4)
34	Kajiado	8 (2.3)
35	Kericho	15 (4.3)
36	Bomet	12 (3.5)
37	Kakamega	14 (4.0)
38	Vihiga	8 (2.3)
39	Bungoma	9 (2.6)
40	Busia	8 (2.3)
41	Siaya	10 (2.9)
42	Kisumu	13 (3.7)
43	Homa Bay	11 (3.2)
44	Migori	5 (1.4)
45	Kisii	21 (6.0)
46	Nyamira	6 (1.7)
47	Nairobi	12 (3.5)
TOTAL		**347 (100)**

All counties in Kenya were represented in the sample except Lamu, Turkana, Marsabit and Mandera. The biggest number of respondents was from Machakos County (40) followed by Makueni (24) and Kisii (21). A Scatter diagram shown below makes the distribution more illustrative.

Figure 4.1: Scatter Diagram Illustrating the National Distribution of Respondents *(n=347)*



The distribution of respondents by Age, Religion and Marital Status are represented in the Tables and Figures below.

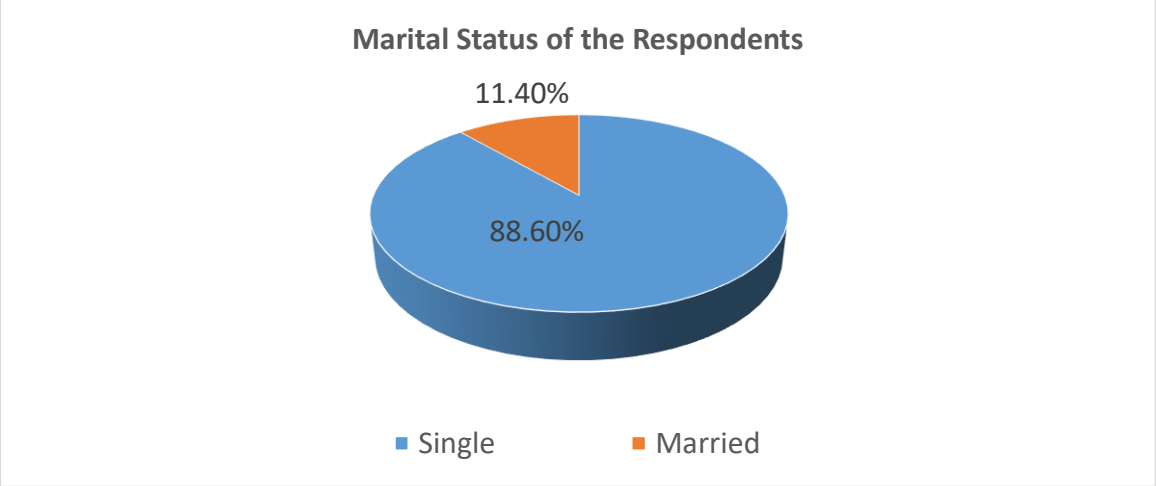
Table 4.3: Distribution of respondents by Age *(n=351)*

Age Bracket (Yrs)	Below 20	20-24	25-29	30 and above	**TOTAL**
Machakos University	53	156	8	0	**217**
Scott Christian University	0	29	1	0	**30**
KMTC Machakos Campus	9	33	17	4	**63**

KMTC Manza Campus	6	31	3	1	**41**
TOTAL (%)	**68 (19.4)**	**248 (70.9)**	**29 (8.3)**	**5 (1.4)**	**351 (100)**

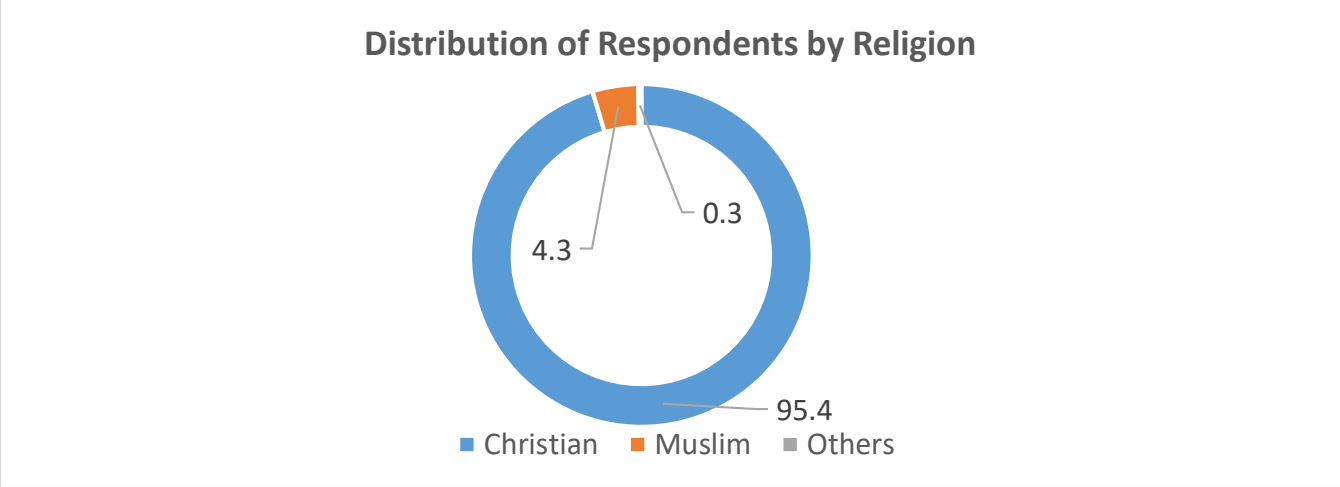
Most of the women participating in this study, being college students, were aged between 20 and 24 years of age, and over 90% were aged below 25 years.

Figure 4.2: Distribution of Respondents by Marital status *(n=350)*



As shown in Fig 4.2, single women made up the largest proportion of the Respondents.

Figure 4.2: Distribution of respondents by Religion *(n=350)*



Most of the Respondents in this study were Christians, making up over 95% of the women interviewed

4.3: Prevalence of PMDD

A Provisional diagnosis of PMDD was made by applying the DSM 5 criteria (see Annex), and the prevalence rate of Provisional PMDD was determined. The findings are summarized in Table 4.6 below:

Table 4.4: Prevalence rate of Provisional PMDD *(n=350)*

Institution	No. with Prov. Diagnosis of PMDD/Total Respondents	% of Total
Machakos University	57/217	26.3
Scott Christian University	11/30	36.7
KMTC Machakos Campus	28/63	44.4
KMTC Manza Campus	14/41	34.1
TOTAL (%)	**110/351**	**31.3**

As seen above, the average prevalence rate of a provisional diagnosis of PMDD in the population studied is 31.3%. The study tested the null hypotheses HO: *There is no significant association between PMDD and age at menarche, menstrual cycle regularity, presence of Dysmenorrhea and contraceptive use*.

An analysis of the selected characteristics (age at menarche, menstrual cycle regularity, dysmenorrhoea and contraceptive use) of the women found to have a provisional diagnosis of PMDD reveals the details as summarized in the following Tables:

Table 4.5: Menarche and PMDD *(n=351)*

Menarche (Yrs of Age)	Total	PMDD (%)	No PMDD (%)	OR	p-Value	95% Confidence Interval	
						Lower	Upper
10-11	4	1 (0.9)	3 (1.2)	-1.08	.167	-1.695	3.785
12-13	96	27 (24.3)	69 (28.7)	-7.46	.270	-8.105	6.752
14-15	176	59 (53.1)	117 (48.7)	4.72	.154	-2.311	7.132
16-17	68	23 (20.7)	45 (18.7)	-2.85	.357	-3.855	1.984
18-19	4	0 (0)	4 (1.7)	-1.78	.256	-1.957	.695
20+	3	1 (0.9)	2 (0.8)	Ref	.	.	.
TOTAL	351	111	240				

Most of the Respondents had their menarche at 14 -15 years of age

Table 4.6: Menstrual Cycle Regularity and PMDD *(n=351)*

Menstrual Cycle	Total	PMDD (%)	No PMDD (%)	OR	p-Value	95% Confidence Interval	
						Lower	Upper
Regular	207	67 (60)	140 (58.3)	-0.144	0.540	-0.603	0.316
Irregular	144	44 (40)	100 (41.7)	Ref	.	.	.
TOTAL	351	111 (100)	240 (100)				

The number of respondents with menstrual cycle irregularity is quite high at almost 50%

Table 4.7: Dysmenorrhoea and PMDD *(n=349)*

Dysmenorrhoea	Total	PMDD (%)	No PMDD (%)	OR	p-Value	95% Confidence Interval	
						Lower	Upper
Present	292 (83.7)	103 (93.6)	189 (79.1)	3.575	0.003	1.559	8.198
Absent	57 (16.3)	7 (6.4)	50 (20.9)	Ref.	.	.	.
TOTAL	349 (100)	110 (100)	239 (100)				

Of note is the finding that Dysmenorrhoea seems to be highly prevalent in the respondents even without considering the provisional diagnosis of PMDD. Further analysis of the association between dysmenorrhea and PMDD showed that there was a significant correlation between the two variables such that individuals with dysmenorrhea had a 3.5 increased risk of having PMDD. This assumed a 95% confidence interval with an upper limit of 8.1 and lower limit of 1.5. The significance level was p = 0.003.

Table 4.8: Contraceptive use and PMDD *(n=349)*

Contraceptive Method	Total	PMDD (%)	No PMDD (%)	OR	p-Value	95% Confidence Interval	
						Lower	Upper
Oral Contraceptive Pill	6 (1.7)	2 (1.8)	4 (1.6)	0.191	0.821	-1.468	1.850
Emergency Contraceptive Pill	31 (8.9)	11 (10.1)	20 (8.3)	0.273	0.552	-0.628	1.175
Injectable	12 (3.4)	3 (2.8)	9 (3.8)	1.577	0.135	-0.493	3.648
Implant	15 (4.3)	5 (4.6)	10 (4.2)	-0.592	0.267	-1.636	0.453
IUCD	3 (0.9)	0 (0)	3 (1.3)	1.665	0.341	-0.415	2.690
Condoms	3 (0.9)	0 (0)	3 (1.3)	-0.725	0.472	-2.701	1.250
None	279 (79.9)	88 (80.7)	191 (79.6)	Ref	.	.	.
TOTAL	349 (100)	109 (100)	240 (100)				

This table shows that a vast majority of the Respondents were not using any form of contraception, and that amongst the users emergency contraception was the preferred method.

4.4: Symptomatology of PMDD

Women with a provisional diagnosis of PMDD expressed the following symptoms, presented in the recognized clusters, as per Table 4:11

Table 4.9: Frequency of various clusters of symptoms of PMDD expressed by Respondents *(n=110)*

Mood Symptoms	Number (%)
Emotional Lability	98 (89.1)
Depressive symptoms	92 (83.6)
Mood swings	91 (82.7)
Irritability	87 (79.1)
Anxiety symptoms	81 (73.6)

Physical Symptoms	Number (%)
Breast tenderness/swelling, Headache, Joint/Muscle Aches, Bloating and Weight Gain	103 (93.6)

Other Symptoms	Number (%)
Loss of interest in Daily activities	77 (70.0)
Loss of Concentration	76 (69.1)
Tiredness/Fatigue	88 (80.0)
Over-Eating	76 (69.1)
Sleep disturbance	81 (73.6)
Loss of control	61 (55.5)

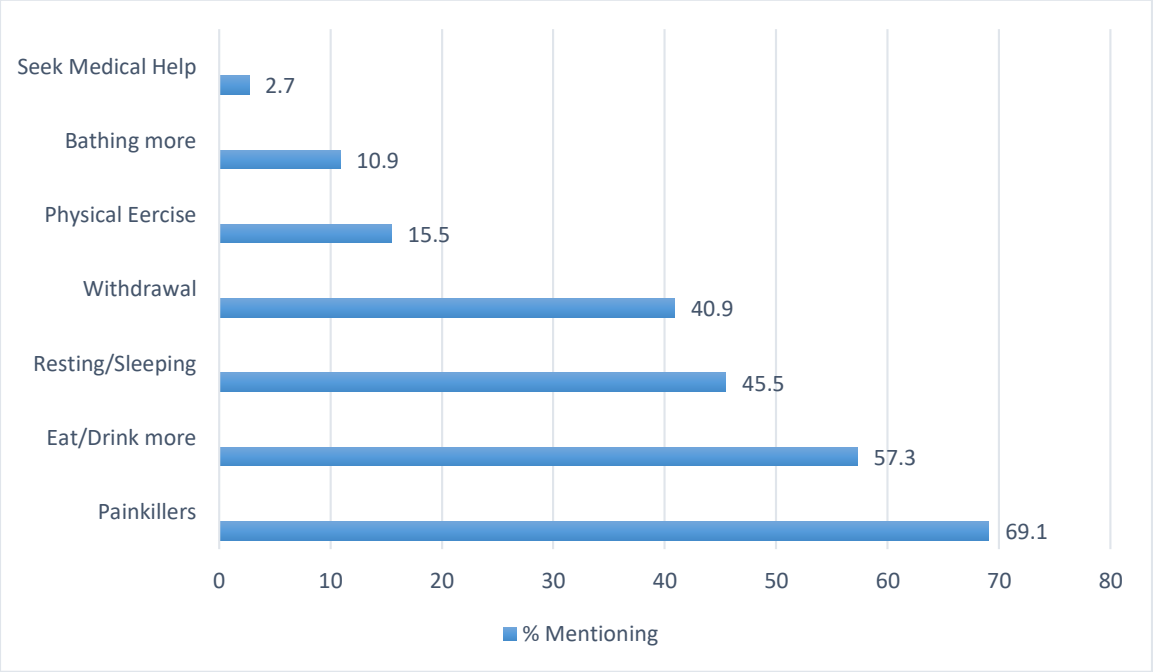
Almost all women with a provisional diagnosis of PMDD expressed physical symptoms.

Emotional lability, mood swings and depression symptoms were also highly expressed.

4.5: Coping Practices in women with PMDD

Respondents expressing symptoms of PMDD were asked to mention various practices they do to alleviate the symptoms. The most frequently mentioned practices are summarized in Table 4.13 below:

Figure 4.4: Coping Practices in women with PMDD



Apparently, painkiller use is the most common practice. Of significant note is the low frequency of the practice of seeking medical help.

CHAPTER FIVE: DISCUSSION

5.1: Introduction

This chapter discusses the findings of this study in comparison with what other workers in the world have found regarding the subject of PMDD. The discussion is thematic based on the specific objectives outlined in chapter Two.

5.2: Prevalence of PMDD

This study found a provisional PMDD prevalence rate of 31.3%. DSM 5 gives two methods of reaching a diagnosis of PMDD: Using a one-time history one may make a provisional diagnosis which may thereafter be confirmed by the second longitudinal method, Daily Rating of Severity of Symptoms (DRSS). The prevalence rate in this study is in agreement with other workers in developing countries. Mishra et al (2015), in India, found a prevalence of 37% in a study of 179 medical students. In an Ethiopian study, the figure was reported to be similarly high at 26.8% (Jember et al, 2017) However, this prevalence is higher than the global rate found by Sepede et al (2016), who reported it as 2 – 8% following a search of a total of 55 PubMed studies on PMDD. Variant prevalence rates have been reported before, for example, De Carvalho et al (2018), doing a community survey using a sample of 727 women aged 18 to 24 years in Brazil, found a prevalence of 17.6% while Mahfoud et al (2018), during a study of a total of 194 women in Qatar reported a prevalence of 15%. This study found that PMDD prevalence is lower in developed countries compared to developing ones. A possible explanation may be the wider availability and use of hormonal contraceptives in developed countries.

Dysmenorrhoea prevalence was quite high in this study with 83.7% of Respondents reporting it. This is in agreement with studies done elsewhere. For example Kitamura et al (2012), reporting from Japan found a prevalence of 85% and Barcikowski et al (2020) in Poland

reported 94%. Significantly, this study found an association between PMDD and Dysmenorrhoea, where the women with PMDD had 3.5 times higher likelihood of having Dysmenorrhoea. The finding is in line with the findings of Kitamura, et al (2012), who reported that the rates of prevalence of PMDD and moderate to severe PMS were increased according to the severity of dysmenorrhea. Jember et al (2017) in Ethiopia and Adewuya et al (2008) in Nigeria also found an association between PMDD and Dysmenorrhoea

This study did not find an association between PMDD and age at menarche although Kamat et al (2019) in India reported that lower age at menarche contributed to PMDD. Similarly, there was no relationship found between menstrual cycle regularity and PMDD although Balik et al (2014) in Turkey asserted that mood changes are related to menstrual problems, notably, menorrhagia, dysmenorrhea, and abnormal menstrual cycle length. Contraceptive use in this study was found to be low (20.1%), and where contraception was used, it was usually the Emergency Contraceptive pill. Amongst the women with PMDD, the rate was in fact lower (19.3%), in spite of the fact that hormonal contraceptives are known to relieve symptoms of PMDD (Eisenlohr-Moul, 2019; Jember et al 2017)

5.3: Symptomatology of PMDD

Mahfoud et al (2018) proposed that presentation of PMDD be categorized in three clusters, namely mood symptoms, physical symptoms and others. This study found that all these clusters were present in the women investigated. Physical symptoms were very prominently expressed.

A major difference between DSM-IV and DSM 5 symptomatology of PMDD is that while DSM-IV gave prominence to depressed mood, DSM 5 prioritized mood lability and irritability (APA, 2000; 2013). This study found that mood lability was expressed by 89.1%

of respondents and irritability by 79.1%, agreeing with DSM 5 on the relative importance of these symptoms.

5.4: Coping Practices of women with PMDD

Human beings possess a natural ability of problem-solving. Women with PMDD will attempt to alleviate their cyclical distress by practicing whatever they believe will relieve their suffering. In this study women gave the various strategies they employ to mitigate their suffering, and of note was the heavy use of over-the-counter painkillers (frequency 69.1%) on one end and the low utilization of medical services (frequency 2.7%). Most of the coping practices reported by women in this study have also been reported elsewhere. A study done in Jordan identified taking analgesics, wearing heavy warm clothes, drinking hot fluids and lying on the abdomen as some of the common such practices (Hamaideh et al, 2013).The reliance on self-medication may indicate several gaps, lack awareness of PMDD as a medical problem being at the forefront. A very recent study by Hantsoo et al (2021) revealed that PMDD is under-recognized by health care providers, can be difficult to diagnose, and lies at the intersection of gynecology and psychiatry, hence ending up being neglected. PMDD has scientifically sound, efficacious and safe modern treatments. Eisenlorh-Moul (2019) identifies SSRIs, Drospirenone-containing oral Contraceptives, Gonadotropin Releasing Hormone (GnRH) analogues, GnRH analogues + Stable Hormone Addback, Total hysterectomy with bilateral salpingo-oophorectomy, Cognitive-Behavioral Therapies as some such approaches. Sadly, these measures require a medical set-up and also trained healthworkers. Needless to say, the women too need to have an attitude of seeking medical help, which this study found grossly lacking.

5.5 Study Limitations

a) A self-administered Questionnaire has limitations in terms of interpretation of the researcher's objectives by the respondent so the data obtained in this study is subjective

b) Some of the information sought could have been better elucidated through in-depth interview or even Focus group discussion

c) Data collected from college students may not necessarily reflect accurately the status of women in Kenya

d) This study had a narrow age range and thus couldn't comprehensively compare the sociodemographic characteristics of women with PMDD vis-à-vis those without

CHAPTER SIX: CONCLUSIONS AND RECOMMENDATIONS

6.1: Conclusions

From the study, the researcher draws the following conclusions:

a) The prevalence of provisional diagnosis of PMDD in the population studied is 31%

b) In the women studied, there was an association between PMDD and Dysmenorrhoea.

c) In the women studied, there was no association between PMDD and age at menarche, contraceptive use nor regularity of menstrual cycle.

d) Emotional lability, depressive symptoms and physical symptoms were commonly expressed by women with PMDD

e) Painkiller use was very prevalent in women with PMDD

f) Medical attention was rarely sought by women with PMDD

6.2: Recommendations

In view of the conclusions, the researcher recommends as follows:

a) Further research in Kenya is needed to accurately determine the prevalence rate of PMDD using a larger, wider sample, and applying a prospective design where the Daily Rating of Severity of Symptoms tool will be used.

b) A study on knowledge, attitude and practices of health providers regarding PMDD is needed to provide baseline data in preparation for the much-needed training on diagnosis and management of PMDD

c) There is an urgent need for sensitization of community members on PMDD and the available medical interventions

d) Making contraception more available to women will lower the prevalence of PMDD

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APPENDICES

Appendix 1: Participant information and Consent Form

KNH-UoN/ERC/FORM/IC01

PARTICIPANT INFORMATION AND CONSENT FORM

Title of study
Premenstrual Dysphoric Disorder: Pattern of morbidity amongst women attending Tertiary Educational Institutions in Machakos Subcounty, Kenya

Principal Investigator
Dr Stanley Nzau Muange, Department of Psychiatry, School of Medicine, College of Health Sciences, University of Nairobi

Introduction
I would like to tell you about a study being conducted by the above listed researcher. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO

This study has been approval by the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. _____

1. **Title of study**
   Premenstrual Dysphoric Disorder: Pattern of morbidity amongst women attending Tertiary Educational Institutions in Machakos Subcounty, Kenya

2. Investigator contacts and roles

Lead Investigator

Dr Stanley Nzau Muange
+254 725 357929/+254 783 3322345
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3. Study introduction

This is a Research in partial fulfilment for the degree of Master of Medicine (Psychiatry), Department of Psychiatry, University of Nairobi

Premenstrual Dysphoric Disorder (PMDD), is a severe mood disorder characterized by cognitive, affective and physical symptoms in the week before onset of menses The global occurence of Premenstrual Dysphoric Disorder has been estimated at 5 in every 100 women This makes it one of the most significant but least addressed gender-specific mental disorder globally

4. Purpose of the study

This study will serve four purposes, namely:

a) Provide baseline information on the disease pattern of Premenstrual Dysphoric Disorder amongst women attending tertiary institutions in Machakos subcounty
b) Make recommendations on practical strategies of mitigating the burden due to Premenstrual Dysphoric Disorder
c) Form a basis for further research on Premenstrual Dysphoric Disorder
d) Fulfill partial requirement for the award of MMed (Psychiatry)

5. Study procedures

This study is being carried out in five institutions of higher learning within Machakos Subcounty, namely: Machakos University, Scott Theological University, Kenya Medical Training College Machakos campus, Kenya Medical Training College Manza Campus and Machakos Teacher Training College. These institutions were selected purposively based on their size and national catchment. Participants for the study have been randomly selected from the enrolment Register, to make up a sample of 301 women aged between 18 – 35 years. You will assist us by filling a questionnaire with 16 questions regarding Premenstrual Dysphoric Disorder. The information you give will be treated with utmost confidentiality and wil be used for research purposes only.

6. Role of the participant

As a participant in this study, you will be requested to provide information about yourself pertaining to the subject under study.

7. **Type of specimens and amount to be obtained where applicable**
   No specimens will be collected from you or anyone else in this study.

8. **Follow up schedules**
   Where a medical problem is discovered during the course of this exercise, necessary action will be taken such as a referral to a health facility competent to handle such.

9. **Benefits**
   As a participant, you will benefit by finding out whether you might be having Premenstrual Dysphoric Disorder, and also help fill a knowledge gap in the diagnosis and management of Premenstrual Dysphoric Disorder and thence broaden the body of medical science.

10. **Risks and discomforts**
    There is no anticipated risk in this activity. The only discomfort will be a little expenditure of time and personal information sharing on the participants' side. This information will be treated with utmost confidence and it will be ensured that no form of identity will appear on the data collection tools.

11. **Confidentiality**
    All information given will be treated with utmost confidentiality. No names will be appended on any documents used.

12. **Voluntary participation**
    Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

13. **Information on researcher and telephone numbers in case of any questions**
    For any questions, feel free to contact the Lead Investigator using the contacts given above or contact KNH-UoN ERC Secretary Contact telephone numbers +254 20 2726300 ext. 44102, email **uonknh_erc@uonbi.**

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with the Lead Investigator. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential. By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes/No

I agree to provide contact information for follow-up: Yes/No

Participant printed name: _____

Participant signature _____ Date _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given her consent.

Researcher's Name: Dr S. Nzau Muange Date: _____

Signature

_____

Role in the study: Lead Investigator

Appendix 2: Data Collection Instruments

QUESTIONNAIRE FOR COLLECTION OF DATA ON PREMENSTRUAL DYSPHORIC DISORDER AMONGST WOMEN IN TERTIARY EDUCATIONAL INSTITUTIONS

"CONFIDENTIAL"

INSTRUCTIONS

Thank you for accepting to participate in this study. The information you give here will be treated with utmost confidentiality and will be used for research purposes only. Kindly, don't write your name or any other identity anywhere in this document

Do you give us consent to proceed? (YES/NO)…….

1. What is your age? (Years) ……
2. What course are you taking? ……
3. What is your marital Status? …….
4. What is your Home County? …….
5. What is your Religion? …….
6. Are you currently getting your monthly periods? (YES/NO)……
7. When did you first start having monthly periods? (Age in years) ……
8. Are your periods regular or irregular? …….
9. Is there any associated low abdominal pains/cramps during your periods? (YES/NO)
10. Have you ever used any form of contraception (Pregnancy-prevention) method?

    (YES/NO)
11. If Yes, are you still using the contraception, and what type (s)……..
12. If you stopped, what was the reason?

    ……..

Now, recall carefully your most recent menstrual periods, then read the symptoms outlined below. Tick all the symptoms below that you experienced during the last 1-2 weeks before your menstrual period started (at least during the most recent two menstrual cycles)

13. In the most recent two (or more) menstrual cycles: (Please **TICK** all applicable)

a) I feel much more depressed, down, tearful, sad or hopeless
b) I feel anxious, tense or nervous
c) I feel hypersensitive to rejection, or, my emotions feel very unstable and unpredictable
d) I feel much more irritable, or I get angry easily
e) My moods swing suddenly

14. In the most recent two (or more) menstrual cycles: (Please **TICK** all applicable)

a) I am much less interested than usual in my hobbies and daily activities
b) I find it much harder to concentrate
c) I feel much more tired and low in energy
d) I tend to crave certain foods, feel hungry all the time, or eat more than usual
e) I find myself tired, oversleeping or taking naps, or, I'm not sleeping well at night
f) I feel very overwhelmed or out of control, like things are too much for me
g) I am bothered by any of the following physical symptoms

    - Breast tenderness or swelling
    - Increased headaches
    - Joint or muscle pain
    - Bloating or water retention
    - Weight gain

15. If you experience any of the symptoms above, answer "yes" or "no" to the following two questions

    1) Do most of the symptoms you noted disappear by the end of your period? (YES/NO)……..
    2) When you are having these symptoms, do they interfere or cause problems in your day-to-day activities or relationships with other persons, including family members? (YES/NO) …….

16. If you experience any of the symptoms above, what do you do to relieve them? (List **ALL**)

……
……
……
……
……..

Thank you very much for the information and your time

Appendix 3: Itemized Budget for the Study

Item	Unit	Unit Cost	Quantity	Total/Ksh
Transport	Mileage	Ksh 100/km	1100 km	**110,000**
Stationery	Print-out	10	5000	**50,000**
Allowances	Per-diem	2000	30	**60,000**
Statutory Payments	Varied	-	-	**5,000**
Contigencies 5%				**11,250**
TOTAL				**236,250**

Appendix 4: Timelines of the Study

	Jan 2019-June 2019	July 2019-Feb 2020	May 2020	June-Oct 2020	Jan - March 202	April-May 2021	June 2021	Sept-Dec 2021
Concept Development								
Proposal Development								
Presentation to Faculty								
Ethical Approval								
Data Collection and Analysis								
Report Writing								
Presentation to Faculty								
Dissemination of Results								

Appendix 5: Map of Machakos Subcounty