COMPARISON BETWEEN MAGNESIUM SUPPLEMENT AND IBUPROFEN AS TREATMENTS OF PRIMARY DYSMENORRHEA AND DIETARY INTAKE OF SCHOOL GOING GIRLS IN MACHAKOS, KENYA: RANDOMIZED TRIAL

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A RESEARCH THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF SCIENCE (FOODS, NUTRITION AND DIETETICS) IN THE SCHOOL OF APPLIED HUMAN SCIENCES OF KENYATTA UNIVERSITY.

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DECLARATION

This thesis is my original work and has not been presented for a degree or any other award in any other university.

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DEDICATION

To the Kenyan adolescent girls with primary dysmenorrhea who dread their menstruation days, for their statistics gave me the energy to carry out this study.

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DEFINITION OF TERMS

Primary dysmenorrhea: This is menstrual dysfunction which begins 1-2 years after menstruation begins, and it is associated with spasmodic contractions of the uterus causing menstrual cramps, nausea and vomiting among adolescent girls (French, 2008).

Pain: An unpleasant sensory and emotional experience associated with actual/ potential tissue damage (Pamplona, 2003).

Severity of Pain: (Operational and subjective) How the girls rated their pain, moderate or severe menstrual pain (Ng'ayu, *et.al.* 1999).

Menarche: The age at which adolescent girls begin to have their first menses. The onset of menstrual periods (Ng'ayu, *et.al.* 1999).

Nulliparous woman: A woman who has never given birth or has never been pregnant Ng'ayu, *et.al.* 1999).

Cramping/ cramps: Pain which radiates and spreads in the part that is affected. It has been related to menstruation (Partrick and Pearce, 2012).

Symptoms: The clinical experiences the adolescent girl has during her menstruation (Ng'ayu, 1999).

Side effects: The signs and symptoms apart from the menstrual related ones; which were experienced by the adolescents especially due to the treatments administered (Kastap, 2000).

Ability to perform daily tasks (operational): the adolescent's capacity to go to class or perform her duties in the school environment (Ng'ayu, *et.al.* 1999).

ABBREVIATIONS AND ACRONYMS

ARHNe	Adolescent Reproductive Health Networks
ASAL	Arid and Semi Arid Lands
CAM	Complementary and Alternative Medicine
CAS	Centre for Adolescent Studies-Kenya
CBS	Central Bureau of Statistics
CI	Confidence Interval
GOK	Government of Kenya
KEMRI	Kenya Medical Research Institute
NSAID's	Non Steroidal Anti Inflammatory Drugs
OR	Odds Ratio
PD	Primary Dysmenorrhea
RDA	Recommended dietary Allowance
SPSS	Statistical Program for Social Sciences
WHO	World Health Organization
Vs	Versus

ABSTRACT

Primary dysmenorrhea refers to painful menstrual cramps accompanied with diarrhea, nausea and vomiting, mood swings and headache. This condition is a leading cause of recurrent class absenteeism with 80.2% of adolescent girls affected in Kenya. The adolescent might not be able to achieve the supplemental dosage (500-1000 mg) for magnesium no matter how much foods rich in magnesium she takes especially during menstruation when she is experiencing nausea and vomiting. Besides, the conventional treatment methods have a failure rate and have often been abused. This study therefore sought to find out nutritional alternatives to treatments of primary dysmenorrhea. The study adopted a randomized trial design with an aim to compare Magnesium supplements and Ibuprofen as treatments on the duration, intensity of menstrual pain, frequency of systemic symptoms, interference on daily activities and the side effects of the two treatments among adolescent girls in Machakos District. Data was cleaned, coded and entered using social statistical package for social sciences. Median, IQR, percentages, chi-square tests, Mann-whitney U, spearman's correlation and Odds ratio ($\alpha = 0.05$) were used for analysis. Findings show that at baseline, those who had pain for a shorter time (1/2 day) were 31% and 30% in magnesium and ibuprofen group respectively. After the second treatment more girls had pain for half a day (85%) in magnesium group and (78%) in ibuprofen group than for 2 days or more (7%) in magnesium group and (8%) in ibuprofen group. At baseline 32% and 40% of adolescents had severe pain in magnesium and ibuprofen group respectively, but due to the effect of the treatments, only 6% and 10% presented with severe pains after the second treatment. At baseline, more than half of the girls were able to do their daily activities in magnesium (62%) and ibuprofen group (64%). After the second treatment, almost all (97%) of the adolescents studied were able to do their daily activities in the two treatment groups. There was a positive improvement after the second treatment for the adolescents who had symptoms of primary dysmenorrhea at baseline. Magnesium had no side effects while Ibuprofen had minor side effects on the girls. The adolescent girls who reported not having taken breakfast everyday had a 2.13 increased likelihood to have severe menstrual pain compared to those who did not take breakfast (OR=2.13;95% CI:0.42-31.57;P=0.002). The respondents who took 3-4 cups of coffee and or black tea and or chocolate beverages had a 1.31 increased likelihood to have severe menstrual pain compared to those who rarely or did not take (OR=1.31; 95% CI: 0.49-3.4; P=0.002). Towards the days of their menses, adolescent girls felt the urge to take sweets, chocolate or juggery. In addition, a regression of the urge to take sweet food was very significant at P=0.003. The odds of having a person who is has severe pains to have the urge to eat sweet foods towards their menstruation was 2.56 times higher than the person who did not have severe pain (that is those who either have moderate or no pain). There is no significant difference in Magnesium and Ibuprofen as treatments of primary dysmenorrhea, Magnesium can therefore be used as a nutrition alternative in the management of period pains.

CHAPTER ONE: INTRODUCTION

1.1 Background of the Study

Dysmenorrhea is a menstrual dysfunction experienced by women worldwide which means painful menses. It is the most common gynaecologic complaint among adolescent girls. There are two types of dysmenorrhea; that is primary and secondary dysmenorrhea. Secondary dysmenorrhea is painful menses that affects women and it is usually associated with an underlying disease; while primary dysmenorrhea affects the young and nulliparous girl. The occurrence of menstruation is a private affair in a woman's life which makes them embarrassed and uncomfortable discussing anything related to menstruation and may not trust their doctor to consider menstrual pain as a real and genuine problem which makes them report every month to the health facility. They therefore reject their pain as something that comes and goes every month. Therefore this study will find out a way that the adolescent can manage menstrual pain by herself.

The prevalence of P.D. is relatively high and varies with regions. According to Harnisch (2009), the prevalence is at 90% of adolescent girls which is slightly higher than values quoted by Sule, *et.al.,* 2007; in a study done in Nigeria which shows 71% prevalence. In Kenya, a similar study was done in Machakos and the prevalence of P.D. was 80.2% (Ngayu, *et. al.*, 1999).

Primary dysmenorrhea is characterized by spasmodic pain which takes several hours. At times it is associated with menstrual pain experienced before menses every month for 3-5 days; accompanied by nausea, vomiting, diarrhea, adverse mood swings, dizziness,

shivering, pain in the lower back and lower abdomen (French, 2008). P.D. does not develop until one has menstruated 4-18 months (1-2 years) into menarche. P.D. is caused by high concentrations of prostaglandins which are produced by nearly all cells in the body. The excessive production of prostaglandins as is the case in primary dysmenorrhea; results into spasmodic contractions of the uterus which intermittently cut off blood flow and deplete oxygen supply to the muscle, causing pain (Pamplona, 2003). Juang, *et. al.,* (2006) has proposed that the extractable substance from the menstruating uterus (prostaglandins) directly stimulate myometrial contractions and could be responsible for primary dysmenorrhea.

Diet has been found to offer relief for the period pains (Bernard, *et. al*., 2006). According to Fujiwara (2009), diet has a long lasting adverse effect on the reproductive function of the adolescent. Excessive intake of caffeine and sugar has been found to increase the severity of menstrual cramps (www.answers.com, 2009). Magnesium supplement has also been researched widely and has been found to have a higher scientific rating in the management of period pains (www.vitaminshoppe.com, 2008). Magnesium works by improving the muscle tone and by reducing the level of prostaglandins and therefore decreasing muscle contractility (Doty & Attaran, 2009). But slightly before menses begin, the level of progesterone (the cell membrane stabilizer) reduces; therefore the intracellular levels of Magnesium(which is a cell membrane stabilizer) reduces too, this further exasperates the muscle contractions, and therefore the menstrual pain worsens (Balbie, *et.al*, 2000). This is therefore the reason why we need to replenish the adolescent girl's Magnesium stores.

Medicines such as the Non-Steroidal Anti-inflammatory Drugs (NSAID's) especially Ibuprofen has been widely used to treat the cramps, it acts by reducing the level of prostaglandins in the body therefore giving relief from the systematic symptoms of painful menses. These drugs have been abused either as over the counter drugs, or taken when the adolescent is at the peak of the pains. Ibuprofen also increases the peripheral blood flow and causes vasodilatation, this therefore reduces the cramps occurrence (www.organisedmedicine.com, 2010).

1.2 Problem Statement and Justification of the Study

About 80.2% of adolescent girls in Kenya suffer P.D. (Ng'ayu, *et.al.*,1999). This makes P.D. the leading cause of recurrent and periodical class absenteeism especially among adolescent girls, which translates to 1-3 days off busy schedules every month due to the symptoms. Primary dysmenorhea can be severe, disabling and may alter the quality of a young girl's life (Zafari *et. al*., 2011). NSAID's, pills and the painkillers have been evident in the adolescent's menstrual pain management. However they too have side effects, with poor compliance, besides the failure rate is often 20-25% (Doty & Attaran, 2009).

According to the KNBS/ICF MACRO (2010), 34% of Kenyan population consist of young people, P.D. treatment should therefore be of great concern to health care policy makers (especially nutritionist). They need to come up with effective alternatives to the treatment of P.D. Without such, adolescent girls will continue suffering physically every

month; which can otherwise be eliminated. Despite the use of medication to treat the symptoms, the pain is most often not completely relieved and comes again in the first day of the next menstrual cycle. It is therefore time to test new therapeutic options to relieve dysmenorrheic pain.

Magnesium is an attractive adjuncture treatment for P.D. Boarding school menus have been found to meet the Magnesium 300 grams RDA requirement for an adolescent girl (Buluku, 2004). Clinical studies show that when study participants were subjected to a 500-1000mg supplemental dosage daily, it reduced the period pains (Proctor & Cynthia, 2006). On the other hand, the adolescent might not be able to achieve the supplemental dose no matter how much foods rich in magnesium she takes especially during menstruation when she is experiencing nausea and vomiting. However, there is paucity of data when it comes to the effect of Magnesium in managing painful menses. Dehnehy (2006) concurs with this and states that there is limited support for the role of Magnesium in alleviating dysmenorrhea related symptoms.

Certain poor dietary habits such as skipping of breakfast and craving for coffee, sweet food and or sugar slightly before menses begin which is common among adolescent girls is another risk factor to period pains. According to findings by (Buluku, 2002), the snacking habits of adolescent girls is inclined towards eating sweet and fast foods available in the school canteen. The adolescents therefore either avoids the school meals and takes what they feel like at this time of their menstrual cycle.

1.3 Purpose of the Study

The aim of the study was to investigate a nutritional alternative to the treatment of P.D. among adolescent girls.

1.4 Objectives of the Study

i). To determine the effect of Magnesium and Ibuprofen treatments on the duration, severity of pain, the symptoms, the side effects and the ability to perform daily activities among the adolescents girls.

ii). To determine the dietary practices which affect the severity of dysmenorrhea among adolescents in Machakos District.

1.5 Research Questions

The study will be guided by the following research questions:

i). How effective is Magnesium supplement or Ibuprofen as treatments of P.D. among adolescents in Machakos district?

ii). Are there dietary practices which increase the severity of menstrual cramps among girls in secondary schools in Machakos district?

1.6 Significance of the Study

The study generated information on the nutritional alternative to treatment of period pains, this may be useful to the Ministry of Education and the Ministry of Health to plan appropriate nutrition education and prescription to girls to alleviate P.D. The Centre for adolescents studies and geriatrics health may also use such information to create awareness among adolescents on the nutritional management of P.D. Health personnel in

secondary institutions may benefit by recommending effective alternative therapy to girls in their institutions.

1.7 Limitations of the Study

The study was conducted in Machakos county, (in only one secondary school); in A.I.C. Nyayo Girls Secondary School among 72 female adolescents who suffer from P.D., which may not be generalized to the whole Machakos. The scores of dysmenorrhea in students with irregular menstruation are significantly higher (66.7%) than those with the regular menstruation (33.3%). Therefore precision was used for the approximate dates of menstruation, in order to know when to give the supplement (http://www.pubmedcentralcanada.com, 2010).

Dysmenorrhea being a very discreet and personal occurrence resulted to very few and shy respondents. Although there are two types of dysmenorrhea, the study focused only on P.D. because of its impact on the adolescent girl in school. Drop out of the subject which was related to relief from pain after taking medication was a confounding factor. Some of the references that were used were old, due to the paucity of data about the management/treatment of primary dysmenorrhea in Kenya.

1.8 Hypotheses of the study

1.8.1 Null Hypothesis

H_0-There is no significant difference in the efficacy of Magnesium supplements and Ibuprofen as treatments of primary dysmenorrhea.

H_0- There is no significant difference in the severity of pain experienced by the dysmenorrheic girls who take excess caffeine and or excess sugar and or skip breakfast and those who do not.

1.8.2 Alternative Hypothesis

H_A- There is significant difference in the efficacy of Magnesium supplements and Ibuprofen as treatments of primary dysmenorrhea.

H_A- There is a significant difference in the severity of pain experienced by the dysmenorrheic girls who take excess caffeine and or excess sugar and or skip breakfast and those who do not.

1.9 Assumptions of the Study

This study was based on the assumption that those who have primary dysmenorrhea may have a way that they deal with their period pains especially if the pain is severe. Another assumption is that there are two kinds of dysmenorrhea, but only one is commonly known as dysmenorrhea because of its common symptoms (severe cramps) to adolescent

girls in high schools. Therefore the inclusion into the study was subjective to the school matron and the experiences that the adolescent girl has during menstruation.

1.10 Conceptual Framework

This study was guided by conceptual framework (Fig 1.1) illustrates how the variables under study relate and influence each other. It portrays the comparison between Magnesium supplements and Ibuprofen intake as treatments of P.D. The severity of P.D. is being assessed in terms of the pain duration and severity, the symptoms and the side effects of the two treatments. These P.D factors are influenced depending on the treatment administered to the adolescent girl. Breakfast intake, caffeine and sugar intake also influence the menstrual pain severity. The symptoms experienced on the day prior to the menses influence the urge for additional sugar and caffeine taken in by the adolescent girl.

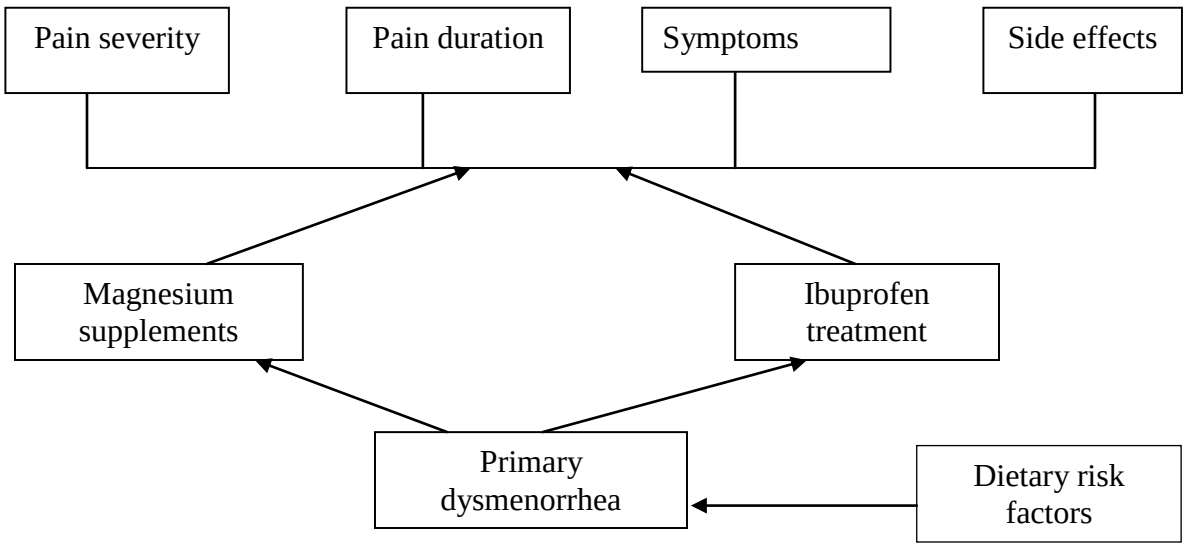

Fig 1.1: A conceptual framework: The effect of treatment on Primary dysmenorrhea

Source: Author, Adapted from (Ng'ayu et.al, 1999; Fujiwara, 2009).

CHAPTER TWO: LITERATURE REVIEW

Literature reviews cover the following areas: Dysmenorrhea, Primary dysmenorrhea (P.D.), the causes, prevalence and treatment by medication and supplementation and the dietary risk factors to P.D.

2.1 Definition of Primary Dysmenorrhea

Dysmenorrhea is the monthly menstrual disorder that occurs to adolescent girls and it is accompanied by vasoconstriction, anorexia and sustained contractions caused by excessive prostaglandins production (Padubidri & Bourni, 2004). Dysmenorrhea also means painful menstrual flow accompanied by a cramping lower abdominal pain with the onset of menstrual flow. Primary dysmenorrhea (P.D.) refers to painful periods that starts 2-3 years after menarche, it begins when the bleeding starts and lasts for 32-48 hours. P.D. is characterized by spasmodic pain resulting into cramps in the lower back and lower abdomen at this time of the month accompanied by nausea, vomiting, diarrhea/ painful bowel movement, adverse mood swings, fatigue and headaches (French, 2008).

2.2 Causes of Primary Dysmenorrhea

In a normal menstrual cycle, the uterus prepares itself for pregnancy. If ovulation comes and goes and there is no foetus to nurture, the uterus will flush its lining. The uterus swells as hormone levels change from less of progesterone to more of prostaglandins. The uterus responds to the prostaglandins by vasoconstriction of the endometrium. This cuts off oxygen supply to the endometrial tissue, the tissue dies and the uterine muscles

contract expelling the uterine lining through the cervix, this is what causes the menstrual bleeding (Partick & Pearce, 2012).

The excessive levels of prostaglandins in the blood is the primary suspect to P.D. Chan & Hill (2008) in their study, determined the menstrual prostaglandin levels from menstrual fluids (in tampons) of non dysmenorrheic and dysmenorrheic subjects, they found out that the prostaglandin level was twice as high in the dysmenorrheic than in the non- dysmenorrheic subjects. When the uterine muscles contracts, it prevents the normal blood supply to the uterus, thus oxygen deprivation to nearby tissues which therefore causing pain (Tortora & Derickson, 2006). Magnesium supplementation can reduce prostaglandin levels which are produced and also improve the muscle tone.

Many theories have explained why it really hurts to menstruate and have related it to the excessive production of prostaglandins (Sloane, 2002). Chudnoff, (2005) suggests that the pain is postulated to the progesterone withdrawal just before the onset of menses, which causes an increase in the prostaglandins production. There are however the risk factors that predispose some women to menstrual pain as opposed to the rest. For example, women who: are 30 years and below, have lower Body Mass Index, experience early menarche, have long and heavy menstrual flow and have poor diet and no exercise, experience more pain (Dawn, 2010). The skipping of breakfast has been researched in many studies, it is still a risk factor to severe menstrual pain. The increased intake of caffeine and sugar also increases the menstrual cramps (www.answers.com, 2009).

2.3 Prevalence of Primary Dysmenorrhea

The prevalence of P.D. varies widely because of differences in diagnosis, definitions of the condition, race and socioeconomic boundaries (Proctor & Cynthia, 2006). Worldwide, a half (50%) of post menarche women experience some degree of dysmenorrhea every time they have their menses. Hazel, (2006) however puts the prevalence worldwide at 67.2%. In the United states, the prevalence of primary dysmenorrhea to be at 90%. Harnisch, (2009) comments that P.D. is as common as to be normative (a normal occurrence). Zafari (2011) concurs with this reports and puts the general incidence of P.D. to be between 40% and 95% in the western countries and 70% to 86% in Iran.

According to studies done in some African secondary schools, the prevalence was rated at 70.4% (Sule, *et. al*., 2007). This compares well with Nigeria's prevalence at 71.1%; but a study done on dysmenorrhea among Muslim women in Nigeria showed that the prevalence was slightly low (36.4%) and it was significantly associated with lower age at menarche and possibly because of the effect caused by the female genital mutilation. In Ethiopia, the prevalence was 74% (Abera, 2004; Sule, *et. al*., 2007). A study done in Eastern Kenya however stated the prevalence at 80.2 % (Ngayu *et.al*., 1999). There is however paucity of data about P.D. and its management especially in Kenya.

2.4 Treatment of Primary Dysmenorrhea

Prostaglandins are produced by nearly all body cells and they influence body functions in so many ways. P.D. can be treated in two main ways, that is by pharmacological means

and also by use of alternative therapies which are non pharmacological in nature (Doty & Attaran, 2009).

2.4.1 Pharmacological treatment

Anti-prostaglandins have been widely used. These are prostaglandin inhibitors which act by suppressing of the menstrual fluids which contain the prostaglandins, and prevent inflammation. These inhibitors can be taken before or at the onset of the pain, then they are also taken every 6-8 hours to prevent the effects of prostaglandins in the first few days of menses (Wendy, 2010).

Non-steroidal anti inflammatory drugs (NSAID's) have been widely used by 80% of the adolescent girls to tame their menstrual pains. Zahradnik, *et. al*, (2010) did a review of 10 different randomized controlled trials assessing NSAID's for treating P.D.; they noted that they are more effective than contraceptives especially for the nulliparous woman. One of the NSAID's is Ibuprofen which when compared to other drugs, has more efficacy and less side effects. French, (2008) noted that Ibuprofen is the drug of choice when administered 2-3 days in each cycle. The author adds that Ibuprofen does not suppress the pituitary ovary, has no metabolic alterations and has been proven to be highly efficacious and effective with less or no side effects.

Ibuprofen prevents the fabrication of prostaglandin, and stopping cyclo oxygenase enzyme resultantly reduces the production of prostaglandin pre-fabrications and thromboxane from arachidonic acid. Pulkkinen & Csapo (2006) also conducted a randomized cross over study on the effect of ibuprofen on the menstrual blood

prostaglandin level in 15 dysmenorrheic women. The 15 women were treated for 12 hours during the first day of their menstrual flow. They were then fitted with a cervical cup for the collection of their menstrual blood for 3 hours. The results however showed that the prostaglandin concentration in the blood collected before treatment was 135±27ng/ml. After the treatment the prostaglandin levels reduced to 24±5ng/ml. There is therefore a causal relationship between effective treatment with Ibuprofen and a decrease in the menstrual blood prostaglandin levels in dysmenorrheic women ($P<0.001$). The question here is the regimen depending on the different levels of severity of P.D.

Side complications of Ibuprofen include: First, digestive and renal complications (Kastap, 2000). Since Ibuprofen has pain relievers in it; these have an effect of altering the signals in the hypothalamus of the brain, where pain is usually registered. Secondly, it also acts by blocking the enzymes, which make the prostaglandins resulting in low levels and consequently no pain nor fever. Thirdly, Ibuprofen acts by increasing the peripheral blood flow causing vasodilation and subsequent reduced heat production during menses (www.organisedwisdom.com, 2010).

Ibuprofen has side effects when wrong dosages are taken especially on the central nervous system, gastric glands, the respiratory system the blood and the skin. Therefore, in case of subjects with heart conditions and digestive problems, Ibuprofen is contraindicated. Most adolescents have developed resistance over time with the pain killers and consequently they go for higher dosages especially when the pain is at its peak. This can be detrimental to their health. The normal dosage of Ibuprofen is 200-400

milligram oral tablets every 4-6 hourly the day before menses, and in the next two days. This is not usually the practice among the adolescents who would rather take pain killers when the pain is at its peak (www.umm.edu, 2010).

2.4.2 Other Therapies/Non Pharmacologic Treatment

Alternative therapies have been used to reduce the period pains. The first and most common and available method is the heat treatments. Most women have found relief by the use a hot water pad or bottle. The pad/bottle is placed at the lower abdomen at the time of the menstrual cramps, it increases the blood flow and decreases muscle spasm. Secondly, exercise has been found in some studies to reduce the prevalence of menstrual pain, especially the exercises involving the pelvic floor. Thirdly, yoga/transcendental meditation have been used to work on the psychological impact of P.D.

Supplementation with Magnesium, zinc, vitamin B6, Vitamin E, Omega 3 Fatty Acids have also been found to relieve the symptoms of P.D. (www.answers.com, 2009). Other non pharmacologic pain managements include spinal manipulations and surgery of the uterus. Oral contraceptives have also been used and have been proved to work by inhibiting ovulation and reducing the prostaglandin level; which results into less uterine cramping (Campbell & Monga, 2000). Therefore, there is a need for available alternatives to these treatments, those which the adolescent girl in an institution set up can access when she knows that her menstrual days are nigh.

2.5 Dietary Intake and Primary Dysmenorrhea

Menstrual pain is colicky in nature and is relieved by good diet (Berek & Novaks, 2007). Variation in food intake across the menstrual cycle has been documented in studies done on human subjects. According to Abraham (1981), there is increased energy and nutrient intake as the menstrual cycle progresses. This would therefore explain the low levels of Magnesium in the muscles, and the resultant premenstrual symptoms. Dalvit (1983) in his study on the effect of the menstrual cycle on nutrient intake found out that there is increased nutrient intake 10 days before menstruation compared to 10 days after the onset of menstruation. This could possibly be because of the change in the hormones responsible for the menstruation. In this study, food intake was therefore studied in terms of breakfast intake, caffeine intake and sugar intake.

Breakfast is the most important meal in a day, 50% of women who do skip this meal have a higher severity of the menstrual cramps. Fujiwara, (2009) suggests that dysmenorrhea is common in women with irregular intake of breakfast. The body needs energy for the day and once the body cannot supply enough, there is stress, the nerves strain, and the transmission of nerve impulses is interfered with resulting into more muscle pain, nausea and diarrhea.

Caffeine contains an aromatic and stimulating substance that causes hyper contraction of muscles resulting into severe pain for the adolescent with menstrual pain. Caffeine causes anxiety and keeps one awake, it therefore makes one more attentive to the pain making them unable to sleep or relax. Fujiwara, (2004) comments that caffeine result into

increased excretion of Magnesium from the body. According to a study which was done on Japan women, the intake of more than 6 cups of coffee in a day result into increased score of menstrual pain (www.ehow.com, 2010). On the contrary, in a double blind placebo controlled study of the efficacy of paracetamol and caffeine combination on women with moderate and severe dysmenorrhea in the treatment of key symptoms of P.D.; caffeine was found out to act as an analgesic and an adjuvant which enhances the efficacy of paracetamol (www.ehow.com, 2010). The question here is, how much coffee is adequate for the adolescent girl to relieve her of her menstrual pains.

Sugar found in most sweet food products is another risk factor to menstrual cramps (Fujiwara, 2007). Premenstrual syndrome is usually associated with craving for too much sugar resulting into eating a lot of chocolate and sweet things just before the menses begin. We also have to bear it in mind that too much sugar; especially the one found in refined foods which students consume a lot, has been researched and found to increase blood lactate level. Blood lactate usually takes the form of lactic acid in the muscles in the inactive muscles such as the pelvic muscle, and thus exasperates the nausea and muscle cramps (Ozerdogan, 2009; www.bodypaincure.com, 2010).

2.7 Magnesium Supplementation

Magnesium is an alkaline earth metal, the second largest cation found in the body between the skeleton and the soft tissues and the greatest muscle relaxing mineral. Magnesium is a nutrient best found in plants than in animal food sources. It is mostly found in whole grains, beans, nuts, seeds, hard tap water, dairy products and in dark

green products. The intake of Magnesium is significantly higher during the menstrual cycle. According to Martini, *et. al. (*1994) the regulation of nutrient intake often changes across the menstrual cycle and is affected by the menstrual cycle hormone. Magnesium intake and output therefore increases with the rise of the menstrual hormone (prostaglandins).

The Recommended Daily Allowance (RDA) of Magnesium for women is 280mg. 60% of Magnesium is in the bone, while the rest circulates in the blood. The body works to keep the Magnesium level in the body constant. Hunt and Johnson (2006) conducted a study on the Magnesium requirements for men and women by cross sectional analyses and found out that Magnesium input is equal to Magnesium output; and this was not affected by age or sex. That would mean that supplementation is the next best alternative when it comes to using Magnesium at the right dosage as a treatment.

About 30% of the total Magnesium is found in green vegetables. Magnesium is stored in the chlorophyll of the green leaves, when the vegetables are overcooked plenty of Magnesium is lost and its bioavailability in the leaf is interfered with. When grains are processed and the germ is removed (like is the case in the school- muthokoi), a lot of Magnesium is also lost. The intake of caffeine has also been researched and found out to interfere with the absorption of Magnesium in the blood.

Prostaglandins are produced from nearly all cells in the body, as a result, controlling its effect in the adolescent's uterus can be an up hill task; therefore supplementation with

Magnesium could be a possible alternative. Magnesium has been widely studied for its effect in the management of P.D., but not in the Kenyan set up. It works by reducing the level of prostaglandin produced and its side effects. Besides the use of pain killers and ovulation inhibitors, the use of Magnesium is a potential nutritional alternative to treat P.D. and the advantage is that it is widely free of side effects. Magnesium use has also resulted into reduction in the absence from work and class absence due to the reduced pain experienced during the periods (Lieberman & Brunning, 2007 ; Doty & Attaran, 2009). Magnesium helps in proper nerve functions and its deficiency results in irritability and muscle pain as in the case of menstrual pain. It also relaxes the muscles and reduces the production of prostaglandins. Its mechanism of action is non-specific; Magnesium may work via a decrease in the level of prostaglandins, or by decreasing the muscle contractility.

According to Dehnehy (2006), there is limited support for the role of Magnesium in alleviating dysmenorrhea symptoms. Though there is paucity of data about the effect of Magnesium in the management of primary dysmenorrhea, few studies have been done which show positive feedback. Women taking Magnesium supplements have been researched and found to have substantially lower levels of prostaglandins in their menstrual fluid compared to their placebo. However the formulation of Magnesium, the method of administration and therapy may vary in each trial (Dehnehy, 2006). Magnesium is also a cell membrane stabilizer and when intracellular levels are reduced as they are when progesterone levels are withdrawn; as it usually occurs on days prior to menses, then muscles become contractile causing the pain.

Magnesium has been found to be the newest therapeutic alternative to manage P.D. according to a preliminary double blind trial (Gorsh & Mulley, 2009 ; www.vitaminshoppe.com, 2009). In a 6 month double blind placebo controlled study of 50 women, 21% of the 25 women showed a reduction in the symptoms, while only 4 reported no improvement (www.healthykey.com, 2009). Similarly in a small, randomized, double blind trial, Magnesium was found to be more effective than the placebos for menstrual relief. When the study persons were subjected to a 500-1000mg supplemental dosage daily, beginning on the first day of menses till the last day of menses, it was noted to reduce significantly the need for additional medication for the period pains (Balbie, *et.al*., 2000 ; Doty & Attaran, 2009;).

The RDA for Magnesium is 280grams but according to Hunt and Johnson (2006) the Magnesium requirement for women is 165 mg per day. That means that in order for one to reach the 500-1000 gram dosage needed for the treatments then they require to have eaten a lot of the foods rich in Magnesium. This is impractical at this time of the month due to nausea associates with the premenstrual symptoms. Secondly, supplements are easy to prescribe and use as opposed to the bulk of the food sources. Thirdly, during pre and menstruation periods, the premenstrual symptoms (nausea and lack of appetite) set in and therefore being able to meet the dietary requirements can be a problem. Lastly, we need the supplements in order to top up the dietary intake which may not be adequate to restore the low levels back to normal. When supplementing, the Magnesium might reach its toxicity level and might cause alkalosis, diarrhea and dehydration. Therefore, the

study subjects needed to take it for a maximum of four days only with a lot of water or fluids. Subjects with cardiac and renal problems are contraindicated.

CHAPTER THREE: METHODOLOGY

This chapter covers the study design, a description of the study site and target population, sampling techniques and procedure, sample size determination and the research instruments. Also presented are details on pre-testing the instruments, the data collection procedures or techniques, variables of the study, ethical consideration for data collection and the procedures for data analysis.

3.1 Research Design

This study was a randomized clinical trial designed to compare Magnesium supplement and Ibuprofen as treatments of P.D. The adolescents who met the selection criteria were 72 girls with primary dysmenorrhea; aged between 14-19 years in Nyayo girls' secondary boarding school, Machakos district.

3.2 Operationalization of Variables

The dependent variables in this study were primary dysmenorrhea, which were measured in terms of the duration of pain, the severity of pain, the ability to perform the daily activities, the symptoms and the side effects of the study. The independent variables were treatment with Magnesium and treatment with Ibuprofen.

3.3 Study Area

The study was carried out in Machakos District, Kautandin Division which was purposefully sampled due to the recommendations given in a cross sectional descriptive

study done in three secondary schools in Machakos by Ngayu *et.al.* (1999), which found out that the prevalence of dysmenorrhea was high (80.2%). A.I.C. Nyayo Girl's Boarding Secondary School was purposefully sampled due to the large student population.

3.4 The Target Population

This study targeted adolescents from A.I.C. Nyayo Girls Boarding Secondary School who would meet the inclusion criteria (Ngayu, *et.al*., 1999; Pamplona, 2003).

3.4.1 Inclusion Criteria

- Adolescent girls in their 14-19 years with established regular menstruation (26-30 days)
- Adolescent girls with known severe or moderate menstrual pain(P.D.)
- Adolescents who gave an informed consent and who were not allergic to Ibuprofen were included in the study
- Adolescents who were nulliparous (had not born a baby) at the time of the study
- Adolescent girls who were available in the boarding institution between January and April 2011 excluding the half term break.
- Adolescent girls who could do without any additional pain killers to manage their menses.

3.4.2 Exclusion Criteria

- Adolescent girls with known chronic disease such as renal or heart disease.

The proportion of adolescents in the school population visiting the school matron every month for pain killers was estimated to be 50% although the actual coverage was unknown (Personal communication, Matron-in-Charge, January, 2011).

3.5 Sampling

3.5.1 Sample Size Determination

Ready medical records from the institution's clinic were accessed, the adolescent girls who had menstrual pain, medically proven were then listed and a study frame of 72 established. The sample frame consisted of 72 girls with 35 subjects in the treatment group one (Magnesium) and 37 subjects in treatment group two (Ibuprofen). According to Gall & Borg, (1993) a 30 and 30 sample is quiet adequate for a comparative study.

3.5.2 Sampling Technique and Procedures

Matching was done by the selection of subjects for the two experimental groups in such a way that they were closely comparable on a pre-test that measures the dependable variable. The following steps were therefore followed during the matching of the two experimental groups. First the subjects were paired based on their scores randomly from 1-72. Secondly, the subjects were randomly assigned one member (the odds) to group one and the other (the even) group. This was done without their knowledge of the treatments and at the first encounter with the subjects. Thirdly, treatment group one were exposed to Magnesium treatment while treatment group two were given an alternate treatment (Ibuprofen). Fourthly, the questionnaires were administered to both groups then the performance of both groups was compared.

3.5.2 Description of the Interventions

3.5.2.1 Preparation for Intervention

The researcher was responsible for interventions which took place inside the school dispensary. Training of the School matron and the adolescent girls were done on days that were convenient to them. The trainings were on the subject under study, research design, objectives and the short term advantages of involving themselves in the study.

Blinding of the study hypothesis was done to the school matron and the study subjects to avoid any likelihood of bias in the way the treatments were administered in the study. The date of the beginning of the last menses and the number of days of bleeding were established before the study. The adolescents who could not predict the initiation of their periods were instructed to start medication as soon as the bleeding started or when menstruation related symptoms occurred.

The school matron administered the treatments with plenty of water to prevent side effects. The adolescents were also instructed to take food before taking the medications to prevent gastric irritation. The adolescent girls reported to the school nurse a day prior to menses (with premenstrual signs), on day one and on day two of menses. They took their treatments and then signed against their names. The treatments went on for two months but once relief was felt; the adolescent girls were then free from taking the next treatments. According to Rees *et. al*. (1984), treatment with NSAID's (Ibuprofen) in a therapeutic dose is preferred. Initial treatment should be tried for at least 3 menstrual

periods. The author also noted that treatment is effective when it starts 1-2 days before the onset of menstruation.

3.5.2.1 Intervention Procedure

This procedure was applicable to both Magnesium (treatment group one) and Ibuprofen (treatment group two). The adolescents in the groups either received 500mg of Magnesium or 200mg of Ibuprofen daily for three days of their menses. The treatments were administered every month on the day before their menstruation (premenstrual symptoms), on the actual day of menstruation and on the second day depending on the number of days the pain was experienced.

Appointments were therefore made with the adolescent for taking the next medications from the school matron's office in the next cycle. This was done after establishing the next days of menstruation. There were follow ups of the adolescents after taking the medication to determine the impact of the treatments on the presence of the pain, the symptoms, the pain severity, the duration, the interference on their daily activities and the side effects of the treatments. The follow up was done after every two weeks depending on the menstrual days of the subjects. Fewer visits were made to treatment group one and treatment group two to minimize possible influence on the adolescent reporting the effect of the treatment.

3.6 Data Collection Procedures

The main instrument used in this study was a semi-structured questionnaire (APPENDIX 2). It is commonly used to study adolescents to provide in depth information. Researcher administered questionnaires were filled to collect the demographic information, duration of pain, severity of pain, side effects of the treatments, the symptoms of primary dysmenorrhea, adolescent's frequency of breakfast intake, intake of caffeine, excess sugar and the urge to take sweet food days before menstruation start.

A total of three interviews were administered by the investigator to both study groups as follows. First, the baseline interview was administered within the first week after enrolment. Secondly, the full dose of the treatments was set aside at the matron's office for the subjects. The study subjects then received drug envelopes each month from the matron, and the possible drug complications were explained to the subjects. They were asked them to refer us (KEMRI, Investigator and matron) if the mentioned complications occurred. The second interview was done within the second week after taking the medication. The treatments were again administered to the adolescents containing the tablets (both Magnesium and Ibuprofen). The third interview was administered to adolescents in the different study groups after taking the treatments within the second month of treatment. The interviews took place inside the matron's office to provide un-interrupted privacy, each interview lasted five to ten minutes. Appointments were made after every interview with the subjects. The researcher and supervisors crosschecked data collected regularly during the data collection period to ensure that any clarifications necessary were made while the research team was still in the field.

3.7 Pre-testing

Pretest was conducted among 10% of adolescent girls in a Machakos girls secondary school due to the comparable dietary and demographic characteristics in Machakos district for one day. The eligibility criteria, the settings and location where data was collected were also pretested. It was however impossible to cover the actual duration of the study (the baseline information was however achieved); but the pre-test was adequate to test all the aspects and procedures. The pretest tested the data collection instrument for length, content, question wording, and language to ensure clarity and accuracy. Validity was ensured by using experts in the field of adolescent health and research. They were requested to assess the relevance of the content used in the questionnaire. Reliability was done by ensuring training of the research team and by supervision from Kenyatta University supervisors (Fisher, John and John, 1983).

3.8 Data Analysis

Data was coded and entered into a micro-computer. Statistical program for Social Sciences for windows version 17 and Microsoft Excel Computer Packages were used. Distributional properties of continuous variables were assessed using Exploratory Data Analysis (EDA). Descriptive summary statistics such as frequencies, median and Inter Quartile Range(IQR) were used to describe the characteristics of the study population. Inferential statistics were used to determine if the study groups had a relationship and comparison in the variables measured at the beginning and end of the study period as shown in Table 3.2.

Non parametric tests such as Pearson’s chi square test, odds ratio, proportions calculator were used to test the relationship between the categorical variables such as the pain

severity, duration, ability to perform daily activities and symptoms of dysmenorrhea. Mann Whitney U test was used for non-normally distributed data to test for the differences between the 2 interventions for continuous variables investigated in the two experimental groups. Mann U test was used, it assumed that the two groups were the same in terms of availability of period pains at the beginning of the study. Spearman's correlations were used to examine the association between the Magnesium supplementation and Ibuprofen treatments and the severity of menstrual pains. In all tests, a P-value of <0.05 was considered significant. Odds ratio was used to determine the ratio of pain severity and dietary characteristics. A proportion calculator was also used to determine significant difference between the two treatments. The analysed data was presented using figures, and tables to provide an overview of the study results.

Table 3.2: Data Analysis

Quantitative				
Descriptive statistics	***Inferential Statistics***			
	Mann Whitney U test	*Odds Ratio*	*Chi square*	*Proportions Calculator*
Weight	Weight	Severity of pain	Age	Duration of pain
Height	Height	Breakfast intake	Weight	Severity of pain
BMI		Sugar intake	Height	
Adolescent age		Caffeine intake	BMI	
Percentages			Age at menarche	

3.9 Ethical Considerations

Research permit was obtained from the Ministry of Education, Kenyatta University(APPENDIX 5) and KEMRI (APPENDIX 4) - the National ethical review committee for human research. Permission was obtained from the Machakos district municipal council, A.I.C. Nyayo girls principal, the class teachers and the school matron. The study objectives and methodologies were explained to them. Informed consent (APPENDIX 1) was sought from the human subjects, for those who were under 18 years old, further consent was sought from their class teachers. Respondents were assured that the data collected will be used for academic purposes only. They were also assured that codes but not names were to be used in the questionnaire for their privacy. According to Horizons, *et.al*. (2005) the ethics should see that the information needed for the study is valid, the researcher therefore looked at the adverse consequences of the study, corrected any procedures, involved the teachers and matron. The Adolescent Reproductive and Health Network(ARHNe) also suggests that the program for studying adolescent must be prompt in order to meet the needs of the adolescent (ARHNe,1999).

CHAPTER FOUR: RESULTS AND DISCUSSIONS

4.1 Demographic Characteristics of Adolescent Girls

There were 76 eligible respondents for the study, 2 of them were lost to follow up due to non-commitment to the study, 1 to total relief from the pain after taking their first medication while 1 was discontinued from the intervention due to inevitable side effects after taking the first treatments. The number that was recruited into the study was 72, that is 35 subjects in magnesium group one and 37 subjects in ibuprofen group.

4.2 Baseline Characteristics

The median age of the adolescent girls was 16 years and 17 years in treatment group one and two respectively. The distribution of the two treatment groups was skewed. At baseline, there was no significant difference between magnesium and ibuprofen group at 95% C.I.

Table 4.1 Baseline Characteristic

Variable	**Intervention**				**P-value**
	Magnesium		**Ibuprofen**		
	Median	**IQR**	**Median**	**IQR**	
Age in Years	16	1	17	1	0.096
Body mass index(BMI)	16.4	6.7	16.9	7.25	0.850
Duration of menstrual flow in days	4	2	3	2	0.070

If P.D. starts 2-3 years after menarche, then these results are not far from the latest Kenya Demographic Health Survey (KNBS/ICF MACRO, 2010), which found out the age at menarche in Kenya to be 12 years. These results also correspond with the work done early by Zeev (2006), who found out the mean age of menarche to be 12.2 years. It is important to emphasize here that an early age of menarche is a risk factor to the occurrence of P.D. among adolescents possibly because of the length of time it takes to expose the uterus to prostaglandins and their side effect.

The median duration of menstrual flow of students during the study was 4 and 3 days respectively. These results reflect that most of the adolescents studied had their menstruation for 4 days. Findings by Ngayu *et. al.*(1999) done in Machakos, concurs with these results that the median duration of menstrual flow was 4 days. The median BMI for both Magnesium and ibuprofen group was below 18.5 kg/m^2 as shown in Table 4.1. Low BMI is a risk factor to primary dysmenorrhea. Ozerdogan *et.al*.(2009) in a study done in Turkey on the predictors of dysmenorrhea among students found out that dysmenorrhea was 1.52 times higher in women who were underweight compared to overweight women (OR=1.52;95%; CI 0.99-2.33). This could be attributed to the weak muscle density of the women with low body mass index.

4.3 Effects of the Treatments

4.3.1 Effects of Treatments on Duration of Pain

At baseline, those who had pain for a shorter time (1/2 day) were 31% and 30% in magnesium and ibuprofen group respectively. After the second treatment more girls had

pain for half a day (85%) in magnesium group and (78%) in ibuprofen group than for 2 days or more (7%) in magnesium group and (8%) in ibuprofen group as shown in figure 4.1 below. At 95% C.I. there was no significant difference between magnesium and ibuprofen in the change of duration of pain experienced by the adolescent girls (P>0.005).

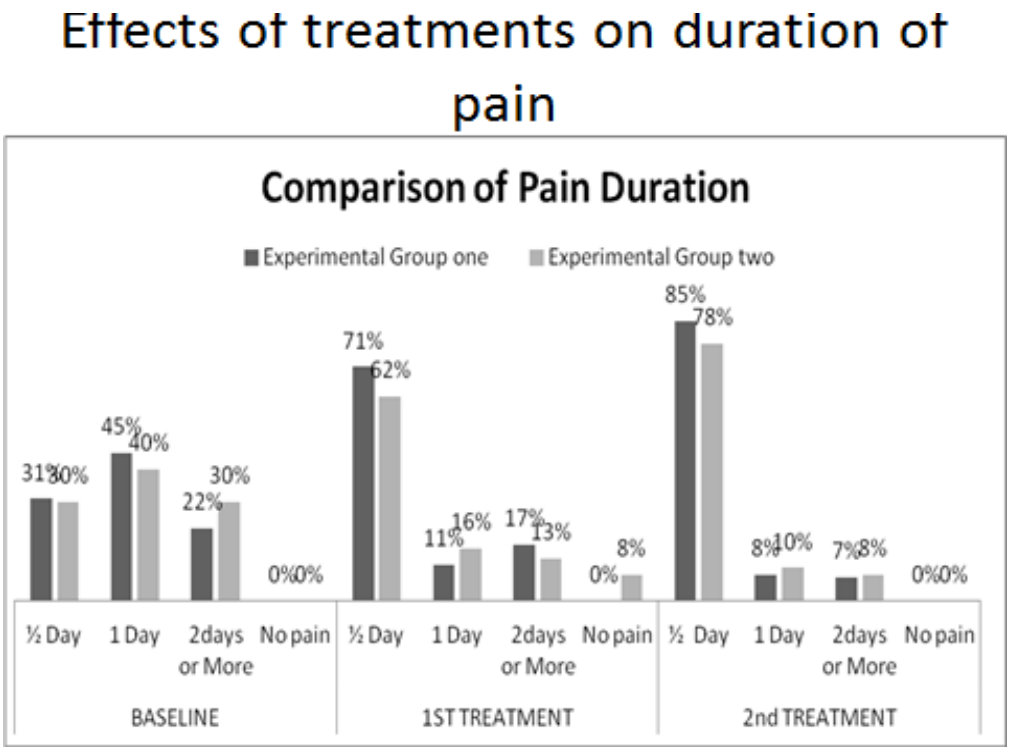

Figure 4.1 Effect of treatment on duration of pain

NSAID's such as Ibuprofen have been widely used by 80% of adolescent girls to tame their menstrual pains. We need to note at this point that Ibuprofen has often been abused by the adolescents who take it either when the pain has already started or when they have so much pain. Most adolescents have developed resistance over time with some pain killers and consequently they go for higher dosages especially when the pain is at its peak in the first day of menstruation. The study findings by Pulkkinen & Csapo (2006) agree

with this in their study which found out that there is a causal relationship between effective treatment with ibuprofen and a decrease in the menstrual blood prostaglandin levels in dysmenorrheic women (P<0.001).

4.3.2 Effects of Treatments on the Severity of Pain

At baseline 32% and 40% of adolescents had severe pain it magnesium and ibuprofen group respectively, but due to the effect of the treatments, only 6% and 10% presented with severe pains after the second treatment as shown in Figure 4.2 below.

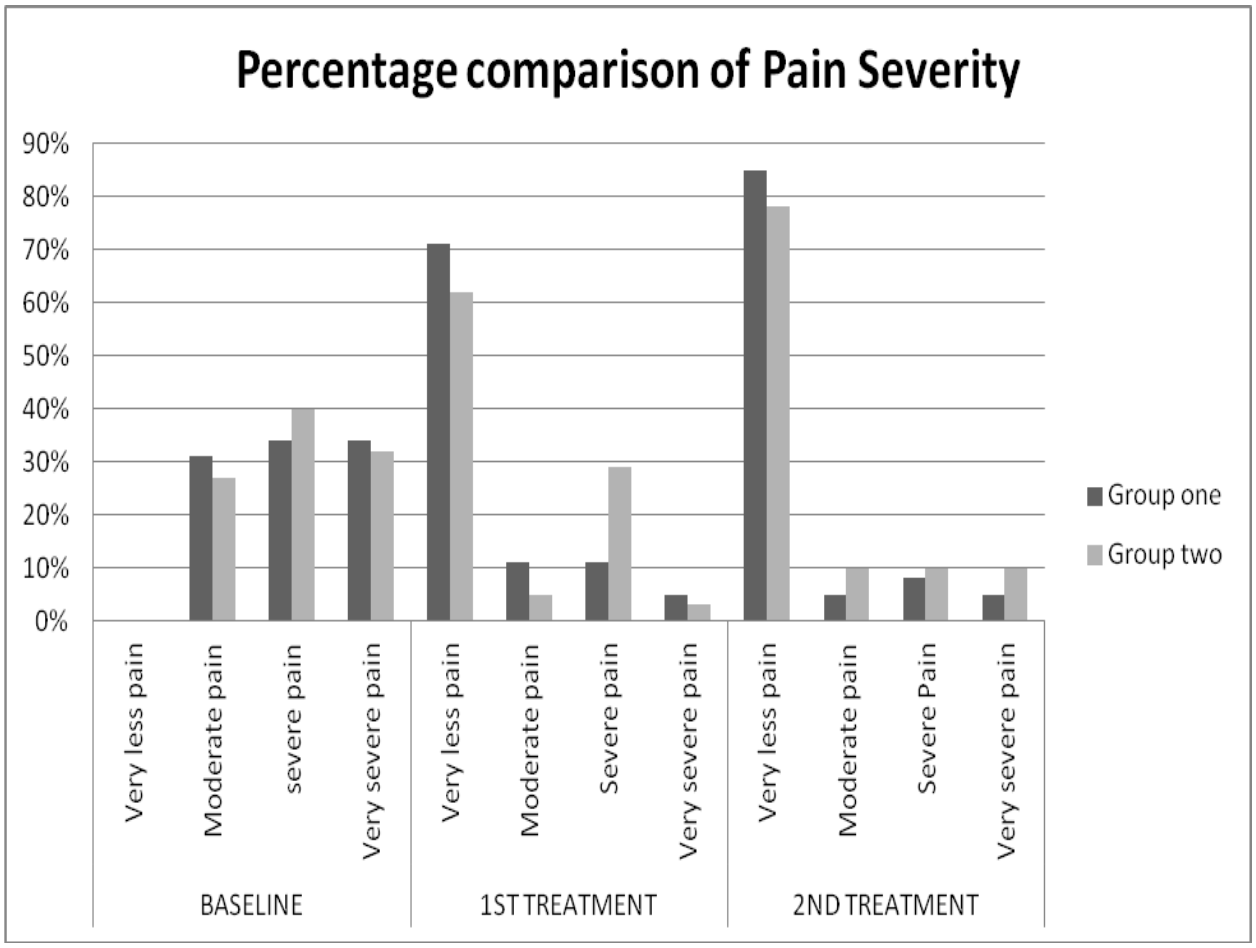

Figure 4.2: Effect of treatment on the Severity of Menstrual Pain

These results could possibly be attributed to the effect the Magnesium and ibuprofen treatment in reducing the severity of pain. There was no significant difference between magnesium and ibuprofen groups in terms of severity of pains experienced by the adolescents with severe pains at 95% significant level (P>0.005). Therefore the use of Magnesium and Ibuprofen would reduce the severity of menstrual pain.

The findings by Balbie, *et. al*. (2000) and Doty, (2009) concur with these results noting that Magnesium works by reducing the level of prostaglandins and therefore it decreases muscle contractility. The lesser the contractility, the less severe the menstrual pain. These results could also be explained by what Lieberman & Brunning (2007) have found that Magnesium works by reducing the level of prostaglandin. Whenever the level of prostaglandin is reduced it counters the severity of menstrual pain. Anti-prostaglandins (ibuprofen) have been widely used to suppress the menstrual fluid containing the prostaglandins.

Since P.D. is caused by high concentrations of prostaglandins which are produced by nearly all cells in the body. Prostaglandins therefore stimulate excessive spasmodic contractions of the uterus, which intermittently cut off blood flow and deplete oxygen supply to the muscle, causing severe pain to the adolescent girl (Pamplona, 2006).

4.3.3 Effects of Treatment on the Ability to do Daily Activities

At baseline, 37% and 35% of girls in magnesium and ibuprofen group respectively were interrupted from their daily activities and therefore were in the dormitories, dispensary or sleeping in class as shown in Table 4.2 below.

Table 4.2 Ability to do Daily Activities before and after Treatment

Group	Baseline		1ST Treatment		2ND Treatment	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**
Treatment Group One	62%	37%	94%	5%	97%	2%
Treatment Group Two	64%	35%	97%	2%	97%	2%

After the first treatment; almost all the girls were able to do their daily school activities in treatment group one (94%) and treatment group two (97%). After the second treatment, there was the increasing ability to do daily activities in every group with almost all the adolescent girls in treatment group one (97%) and treatment group two (97%) were able to do their daily activities. This could possibly be because of the relief from menstrual related symptoms experienced by the adolescent girls because of the medications given.

P.D. related symptoms cause a lot of school absenteeism and the inability to perform daily activities. In Kenya many (80.2%) adolescent girls suffer P.D. which is the leading cause of recurrent/periodical class absenteeism discreetly known to the adolescent girl. These symptoms translates to 1-3 days off busy school schedules every month. Findings

by Zafari *et. al*., 2011 concurs stating that P.D. can alter the quality of a young girl's life. On the contrary findings by Campbell &Monga, (2000) states that in at least 10% of women; menstrual pain is so severe that it interferes with normal day activities. While Schroeder, (1999) reports the class absenteeism related to dysmenorrhea at 23.4%, which is relatively low.

4.4 Effects of Treatments on the Symptoms of Primary Dysmenorrhea

Primary dysmenorrhea is evident by spasmodic pain resulting into cramping lower back and abdominal pain, accompanied by nausea, vomiting, diarrhoea, adverse mood swings, dizziness and shivering (http://familydoctor.org, 2009).

4.4.1 Diarrhoea

At baseline few (11%) girls reported having diarrhea in the Magnesium group while relatively fewer girls (8%) were from the ibuprofen group as shown in Table 4.3. After the first treatment, 8% of the girls studied still reported having period related diarrhea both in the Magnesium and ibuprofen group. With the second treatment; there was no adolescent in Magnesium group that had diarrhoea while in the ibuprofen there were still 8% of the girls having diarrhea. This could possibly be because of the effect of Magnesium in the autonomic nervous system, which controls both vomiting and diarrhoea in the human body. The spasmodic pain experienced by the adolescent is often accompanied by diarrhea especially in the first day of menstruation where the frequency of diarrhoea is high (http://familydoctor.org, 2009).

Table 4.3: The effect of the treatment on the symptoms of primary dysmenorrhea

	Effect Of Treatment On Symptoms					
	Before use (%)		**1ST treatment (%)**		**2ND treatment (%)**	
	T 1	T2	T1	T2	T1	T 2
Diarrhoea	11	8	3	8	0	8
Nausea and vomiting	14	11	0	5	0	3
Cramps	46	46	9	22	6	5
Headache	43	35	11	8	9	5
Mood swings	37	35	14	5	3	5
No pain	0	0	71	62	86	81

*****T1- Magnesium treatment group
*T2- Ibuprofen treatment group

4.4.2 Nausea and Vomiting

Before the intervention, very few girls reported having nausea and or vomiting in magnesium group (14%) and ibuprofen group (11%) as shown in Table 4.3. After the first treatment, magnesium group had none of the girls feeling nauseated and or vomiting during their menses, while ibuprofen treatment group still had few (5%) with nausea and or vomiting. The second treatment left none of the adolescents in magnesium treatment group (0%) having nausea while few in ibuprofen group still experienced nausea and vomiting.

Magnesium offers relatively faster relief from nausea and vomiting during menstruation compared to Ibuprofen. This could be explained by the effect of Magnesium on the autonomic nervous system and in reducing the level of prostaglandin in blood. During menstruation; slightly before bleeding occurs, the adolescent girls may have the feeling of vomiting. This is preceded by spasmodic pain in the body, then a feeling of nausea and vomiting. High Prostaglandin level in the uterus results into inflammatory response. Inflammation produces both cramps, headache, nausea and vomiting to the adolescent girl (Zeev, 2006; Pearce, 2012).

4.4.3 Cramps

At baseline, almost half of the girls studied (46%) had menstrual cramps in both treatment group one and two. After the first treatment, there were fewer girls having menstrual cramps in magnesium group (9%) and ibuprofen group (22%). Table 4.3 also shows that, after the second treatment; the number of girls still affected by cramps decreased in magnesium group (6%) and ibuprofen group (5%). The magnesium group had a reduction in the cases having cramps after the first treatment. This could be possibly because of the reduction in the level of prostaglandins and the effect of Magnesium in reducing muscle spasms. Prostaglandins cause excessive vasoconstriction and myometrial contractions. This leads to ischaemia and pain, thus the adolescent girl will feel the pain as cramps especially in the uterine and abdominal muscles (Zeev, 2006).

4.4.4 Headache

There was a relief from headache experienced by the treatment group one from 43% to 11% in the first month of treatment followed by Ibuprofen group who had a drop from 35% to 5% of the girls suffering headache as shown by the results in Table 4.3. After the second treatment, there were few adolescents with headache in treatment one (9%) and treatment two (5%). This reduction in the cases of headache could be attributed to the effect in the treatments to reduce the hormone (leukotrines) in the blood responsible for inflammation, and thus reducing headache bouts.

4.4.5 Mood swings

Results in Table 4.3 show that at baseline, there were less than half of the adolescents having mood swings in magnesium group (37%) and ibuprofen group (35%). After the second treatment, the mood swings reduced in both magnesium group (14%) and ibuprofen group (8%). After the second treatment, there were very few adolescents with mood swings in magnesium group (3%) and ibuprofen treatment group (5%).

4.4.6 Other pain related symptoms

All the girls (100%) had pain related symptoms at the beginning of the study. The results in Table 4.3 show that; after the first month treatment, almost a third of the girls had pain related symptoms in magnesium treatment group (29%) and in ibuprofen treatment group (38%). After the second treatment, the percentages reduced to almost a quarter of the adolescents in magnesium group (14%) and in ibuprofen group (19%) of the girls reporting pain related symptoms. Rees *et. al*. (1984) in their study on the prostaglandins in the menstrual fluid in menorrhagia and dysmenorrhea, found out that without

medications, there is usually 4 times more prostaglandins in the blood during the first day of menstruation. This probably explains the pain experienced on the first day of menstruation, the adolescent usually feels a lot of pain in the abdomen, on the thigh, abdomen, breast and in the uterus.

4.5 Side Effects of the Treatments

Side effects were explained as the signs and symptoms apart from the menstrual related ones; which were experienced by the adolescents especially due to the treatments administered. Magnesium had no side effects on the adolescent girls studied, both after the first and the second treatments. The use of Magnesium is a potential natural opportunity to treat primary dysmenorrhea and the advantage is that it is widely free of side effects. 3% of the adolescents in ibuprofen group experienced side effect in the first month of treatment as shown in Table 4.4 below.

Table 4.4: Side Effects of Magnesium and Ibuprofen treatments

BASE	**After 1st Treatment**		**After 2nd Treatment**	
	No (%)	**Yes (%)**	**No (%)**	**Yes (%)**
Treatment Group One	100	0	100	0
Treatment group Two	97	3	92	8

The adolescents (3%) complained of swollen stomachs and rashes in the skin. The number of girls with side effects increased to 8% with ibuprofen use. Ibuprofen has side

effects when wrong dosages are taken especially on the central nervous system, gastric glands and the skin. According to Kastap (2000) Ibuprofen has complications affecting the digestive organs and the kidney. This could possibly explain the stomach pain and the skin rashes experienced by the girls after taking the ibuprofen treatments.

4.6 Effect of Dietary Practices on the Severity of Menstrual Pain

4.6.1 Breakfast Intake

At baseline, the adolescent girls who never took breakfast everyday had a 2.13 increased likelihood to have severe menstrual pain compared to those who rarely take breakfast (OR=2.13;95% CI:0.42-31.57;P=0.002) as shown in Table 4.7. The adolescents who never took breakfast had severe menstrual cramps in magnesium group (100%) and half of the girls in ibuprofen group (50%). While only a third of the adolescents who took breakfast everyday had severe menstrual pain in magnesium group (34%) and ibuprofen group (41%) as shown in Table 4.5.

Table 4.5: The Effect of Breakfast Intake on the Severity of Pain

Group		Total	Breakfast intake			
			Every day (%)	**Six times every week (%)**	**Once a week (%)**	**Never (%)**
Group One	**Very severe**	34%	38	0	33	0
	Severe	34%	31	50	33	100
	Moderate pain	31%	31	50	33	0
Group two	**Very severe**	32%	31	0	50	50
	Severe	41%	38	100	50	50
	Moderate pain	27%	31	0	0	0

These results are consistent with Makaleler *et. al*. (2009) in their study on the risk factors associated with P.D. among adolescents in Georgia where they found out that the women who skip meals reported a marked increase in dysmenorrhea compared to women who reported no skipping of meals (59.78% vs 27.03%, P<0.001). These results could probably be associated with the fact that after 6-8 hours of sleeping, breaking the fast is very necessary because the body needs energy to start the day again.

The skipping of breakfast has been researched in many studies and found to increases the severity of cramps (http://www.answers.com, 2009). Fujiwara (2009) concurs and states that dysmenorrhea (painful menses) is common in women with irregular intake of breakfast. This could possibly be attributed to the body inability to supply enough energy, therefore causing stress, nerves strain, and this interferes with the transmission of nerve impulses resulting into more muscle cramps, nausea and diarrhoea. Days before the menstruation begins; the energy consumption usually increases. This means that in case an adolescent has the habit of skipping breakfast, there can be energy imbalance hence more strain in the body and thus more pain experienced by the adolescent.

The level of activity before the premenstrual symptoms set in is usually very high, in the ten days before the onset of menstruation. Then if the adolescent does not eat well, there will be a deficit in the energy level of the adolescent, this could translate to head aches, nausea and general weakness of the body. Lissner, *et. al.*(2009) and Webb (2012) in their previous work on the 24-hour energy expenditure and the menstrual cycle correspond

with this; they both found out that the energy expenditure increases in magnitude at the premenstrual time.

4.6.2 Coffee, Black Tea and Chocolate Intake

The adolescent girls who took 3-4 cups of coffee and or black tea and or chocolate beverages had a 1.31 increased likelihood to have severe menstrual pain compared to those who rarely or do not take (OR=1.31; 95% CI: 0.49-3.4; p=0.002) as shown in Table 4.7 According to Unsul *et.al.* (2010) those who take coffee were 2.08 more times to suffer from P.D. than those who do not take coffee. Most of the adolescents studied who reported taking 2 or more cups of either coffee or black tea had higher chances of having moderate pain in magnesium group (50%) and ibuprofen group (100%), as shown in Table 4.6.

Table 4.6: The Effect of Coffee, Tea and Chocolate Intake on the Severity of Pain

Group		No. of cups of Coffee/black tea/chocolate daily consumption		
		None (%)	Once (%)	Twice (%)
Group one	Very severe	29	43	25
	Severe	53	14	25
	Moderate Pain	18	43	50
Group two	Very severe	31	40	0
	Severe	35	60	0
	Moderate Pain	35	0	100

A third of the adolescents who reported to have been taking no coffee or tea exhibited moderate menstrual pain in treatment group one (29%) and treatment two (31%). These results therefore show that the higher the amount of caffeine taken, the higher the chances of menstrual pain. Caffeine(in tea, coffee or chocolate) contains an aromatic and stimulating substance which causes excessive contraction of the pelvic floor muscles. More often than not when the adolescent girl nears their menstrual periods; they crave for the caffeinated drinks often resulting into more pain for the adolescent with menstrual pain because of the residual effect of caffeine. Balbie *et.al.* (1993) in their findings which concur that there is significant increase in the consumption of carbonated and caffeinated beverages in the luteal phase (pre-menstrual phase) of the menstrual cycle. Caffeine causes anxiety and keeps one very alert, it therefore makes one more attentive to the pain therefore making them unable to sleep or relax. This is especially in the first day of menses when the menstrual cramps are at their peak. In addition, caffeine has also been found to result into increased excretion of Magnesium from the body. Magnesium has been researched and found to reduce the level of prostaglandin in the blood. Therefore, the adolescent girl who consumes coffee and or chocolate is at risk of more menstrual cramps.

Diamond *et. al*. (2000) found out that when ibuprofen and caffeine are administered together provides significantly greater analgesic activity than Ibuprofen alone and caffeine alone. This means that caffeine can only be used as an adjunctive treatment but not as a beverage or a drug for managing period pains. The adolescent girls who drunk coca cola had a 1.65 increased likelihood to have severe menstrual pain compared to

those who rarely drunk or did not (OR=1.65; 95% CI: 0.46-5.87; P=0.44) as shown in Table 4.7 below. This could probably be attributed to the very high caffeine and sugar level in the drink.

Table 4.7: Univariate Analysis of the Dietary Intake and the Severity of Menstrual Pain

Independent Variable	***Severe Menstrual pain***		
	Odds Ratio	*95% CI*	*P- value*
Poor Breakfast Intake	2.13	0.42-31.57	0.002
Coffee, Black tea, Chocolate Intake	1.31	0.49-3.4	0.002
Coca Cola Intake	1.65	0.46-5.87	0.44
Sugar Intake	2.13	0.18-6.28	0.002

4.6.3 Sugar Intake

The results of this study reveal that towards the onset of menses, adolescent girls feel the urge to take sweets, chocolate or juggery. The regression of the urge to take sweet food is very significant at P=0.003. The adolescent girls who usually take 3-4 teaspoons of sugar in their beverages had a 2.13 increased likelihood to have severe menstrual pain compared to those who take lesser or do not take sugar (OR=2.13; 95% CI: 0.18-6.28; P=0.002) as shown in Table 4.7.

This study also reveals that the odds of having a person in severe pains to have the urge to eat sweet foods towards their menstruation was 2.56 times higher than the person who does not have severe pain(that is those who either have moderate or no pain). Ozerdogan *et.al.*(2009) in their study on the predictors of dysmenorrhea among students found out that dysmenorrhea was 1.8 times higher in women with an excessive sugar intake compared to those who reported no sugar intake (OR=1.77;95% CI: 1.15-2.72).

Table 4.8 also shown that the adolescents who reported to have been taking no sugar in their beverage had moderate menstrual pain in treatment group one (100%). In treatment group two, almost two thirds (60%) of the adolescents reported very severe menstrual pain upon the consumption of beverages without sugar. Few of the adolescents reported moderate menstrual pain in treatment group one (45%) and treatment group two (36%) after they added three teaspoons of sugar into their beverage. In the days prior to their menses; almost a third of the adolescents with very severe menstrual cramps had the urge to take chocolate, sweet food or juggery in treatment group one (37%) and in treatment group two (29%).

4.8 The Effect of Sugar Intake on the Severity of Menstrual Pain.

Group		Number of tea spoons of sugar added into a cup of beverage				The feeling to eat of sweet foods towards menstruation days (chocolate, soda, juggery)	
		None(%)	One (%)	Two (%)	Three (%)	Yes (%)	No (%)
Group one	very severe	0	25	47	18	37	31
	severe	0	50	32	36	21	50
	moderate pain	100	25	21	45	42	19
Group two	very severe	60	13	31	36	29	38
	severe	20	63	46	27	42	38
	moderate pain	20	25	23	36	29	23

In a study by Makaleler, *et.al.* (2009) the women who reported an increased sugar intake reported a marked increase of dysmenorrhea compared to women reporting no sugar intake (55.61% vs 44.39%, P=0.0023). The results also show that the girls mix sugar, blue band and cocoa and take it to quench their desire to take something sweet slightly before their menses begin. Increased intake of sugar and or sweet things has been researched widely and found to increase the severity of menstrual cramps (http://www.answers.com, 2009).

Premenstrual syndrome is usually associated with too much sugar craving resulting into eating a lot of juggery, chocolate and sweet things just before the menses. According to Fujiwara (2009), sugar found in most sweet food products increases the severity of menstrual cramps. Ozerdogan (2009) and Barnard (2006) observe that too much sugar, especially the one found in refined/ or added to processed foods which students consume a lot, has been researched and found to increase blood lactate level. Blood lactate then takes the form of lactic acid in the muscles (especially the inactive muscles such as the pelvic muscle). Excess levels of lactic acid can cause muscle cramps. Bernard (2006) comments that in the 14 days before periods are due to begin, the adolescents should cut down on their sugar, salt and caffeine intake.

CHAPTER FIVE: SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1 Summary

5.1.1 Demographic Characteristics

The medial age at menarche was 16 and 17 years for magnesium and ibuprofen respectively. In both treatment groups, all study participants had BMI below 18.5 kg/m^2. The duration of menstrual flow was 4 days, long menstrual days predisposed the adolescent to severe menstrual pain.

5.1.2 The Effect of the Treatment on the Duration of Pain

At baseline, those who had pain for a shorter time (1/2 day) were 31% and 30% in magnesium and ibuprofen group respectively. After the second treatment more girls had pain for half a day (85%) in magnesium group and (78%) in ibuprofen group than for 2 days or more (7%) in magnesium group and (8%) in ibuprofen group. At 95% C.I. there was no significant difference between magnesium and ibuprofen in the change of duration of pain experienced by the adolescent girls ($P>0.005$). These findings therefore accept the null hypothesis that there is no significant difference in the efficacy of Magnesium supplements and Ibuprofen as treatments of P.D.

5.1.3 The Effect of the Treatment on the Severity of Pain

At baseline 32% and 40% of adolescents had severe pain it magnesium and ibuprofen group respectively, but due to the effect of the treatments, only 6% and 10% presented

with severe pains after the second treatment. These findings therefore accept the null hypothesis that there is no significant difference in the efficacy of Magnesium supplements and Ibuprofen (Ibuprofen) as treatments of P.D

5.1.4 The Effect of the Treatment on the Symptoms and the Ability to do Daily Activities

At baseline, more than a third of the girls were not able to do their daily activities in magnesium (38%) and ibuprofen group (36%). At the end of the study, almost all the adolescent girls (97%) were able to do their daily school activities after the first and the second treatments with both Magnesium and Ibuprofen treatment. There was positive improvement (from baseline and the second treatment time) on the adolescents who had symptoms of P.D especially diarrhea, nausea and vomiting and mood swings.

5.1.5 The Side Effects of the Treatments

The use of Magnesium is a potential natural opportunity to treat P.D. The advantage is that it is widely free of side effects. Ibuprofen had 3% of the adolescents experiencing side effects in the first month of treatment presenting as rashes.

5.1.6 Effect of Dietary Practices on the Severity of Menstrual Pain

At baseline, the adolescent girls who did not take breakfast everyday had a 2.13 increased likelihood to have severe menstrual pain compared to those who rarely or did take breakfast (OR=2.13;95% CI:0.42-31.57;P=0.002). The results also reveal that, the adolescent girls who take 3-4 cups of coffee and or black tea and or chocolate beverages

had a 1.31 increased likelihood to have severe menstrual pain compared to those who did not (OR=1.31; 95% CI: 0.49-3.4; P=0.002). This study also reveals that the odds of having a person who has severe pains to have the urge to eat sweet foods towards their menstruation was 2.56 times higher than the person who did not have severe pain (that is those who either had moderate or not). This study therefore is in agreement with the alternative Hypothesis which stated that there is a significant difference in the severity of pain experienced by the dysmenorrheic girls who take excess caffeine and or excess sugar and or skip breakfast and those who do not.

5.2 Conclusions

This study therefore concludes that Magnesium and Ibuprofen reduces the duration, the severity of pain and the symptoms that the adolescent girl with primary dysmenorrhea has every month. Therefore Magnesium compares well with Ibuprofen as an alternate treatment of primary dysmenorrhea despite Ibuprofen having minor side effects. Certain dietary practices such as the skipping of breakfast; the intake of 3 or more cups of stimulants (coffee, black tea, chocolate) in a day and excessive sugar intake increases the severity of menstrual pain experienced by the adolescent girl.

5.3 Recommendations

5.3.1 Recommendations for Practice

- This study pointed out to the need to create awareness on the problem of treating period pains among the school going adolescents by the Government of Kenya, Ministry of Health, Department of Nutrition. This awareness would focus more

on the use of magnesium in treatment as well as practicing proper dietary intake. Such information can also be used by the Ministry of Education in collaboration with the principals of girls secondary school should ensure that magnesium is used as a nutrition alternative in the treatment of period pains. The cost implication of using magnesium rather than ibuprofen would be that magnesium needs to be bought in bulk.

5.3.2 Recommendations for further research

- Due to the high prevalence of primary dysmenorrhea in the study population, a similar study can be done in other parts especially a population with similar characteristics. Since this study did not put into consideration other nutrients used in treatments, there is need for a replica study to be conducted. Also a comparative study on the dietary practices of adolescents with and without severe menstrual pain: during and after menstruation.

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APPENDICES

APPENDIX 1: INFORMED CONSENT EXPLANATION

1. TITLE: COMPARISON BETWEEN MAGNESIUM SUPPLEMENT AND IBUPROFEN(IBUPROFEN) AS TREATMENTS OF PRIMARY DYSMENORRHEA AMONG ADOLESCENT GIRLS IN MACHAKOS DISTRICT, KENYA.

2. INTRODUCTION.
I am Gogi Julie, a Master's of Science student at Kenyatta University, in the department of Foods, Nutrition and Dietetics. I am doing my study on the comparison of Magnesium supplements and Ibuprofen as treatments to reduce the monthly period pains among adolescent girls like you in High schools in Machakos District, this area. You can choose to engage yourself in the study.

3. PURPOSE.
The study will find out the efficacy of Magnesium supplements and Ibuprofen as treatments of period pains among adolescent girls like you here in Machakos district.

4. PROCEDURES
The number of adolescents who will be studied including you will be 90 from Machakos District. The supplements and the drugs which are registered for use in Kenya, will be given to you from the school dispensary; a day before your menses, the day you begin your menses and on day two of your menses.

5. BENEFITS AND COMPENSATION
You will not be required to pay anything to get involved in the study. There will be relief in the menstrual pain if you follow instructions. However, after the study, there will be no benefits or compensation which will be given to you in cash or in kind.

6. RISKS
The supplements should be taken with a lot of water for they could cause dehydration and stomach upset. But in case of loosing a lot of water and diarrhoea during these three days of the study; you are free to see us.

7. CONFIDENTIALITY
The information you will give here will be for research purposes only. You are therefore required not to write your name anywhere in the papers. You will however be given research codes.

In case you have questions about this study, please contact the investigator on mobile number (0723 349 666). In case you have questions on your rights to participate in the study, kindly contact KEMRI Secretary (2722541,0722205901,0733400003)
I agree to involve myself in the study for the stated duration of time.
Signature: _____
Date: _____

APPENDIX 2: QUESTIONNAIRE

I am a Foods, Nutrition and Dietetics Masters student at Kenyatta University, carrying out a research on comparison between Magnesium supplement and ibuprofen(Ibuprofen) as treatments of primary dysmenorrhea among adolescent girls in Machakos district, Kenya. The information you give will be treated with utmost confidentiality.

I request you to answer the questions as precisely as possible. Write in answers where the term "other" has been used or tick the appropriate response(s) where answers are provided.

ADMINISTRATIVE DETAILS

Questionnaire ID No……

Name of interviewer……

Date interviewed……..

Questionnaire Checked……Date Checked……..

Section A: Demographic data

A1. How old are you? …….. Years.

A2. When did you begin having your menses? ……...Years.

A3. When were the dates of the beginning of your last menses?.....

A4.How long does the bleeding take?.....

A5. Comment on your level of exercise?.....

…….

Section B: Medical Information

B1. Do you experience the menstrual pains?

1=Yes [ ]
2=No [ ]

B2. In which part(s) of your body do you feel the pain?

1=Lower abdomen [ ]
2=Head [ ]
3=Lower back [ ]
4=Genital parts [ ]
5=Inner thighs [ ]
6=Pelvis [ ]
7=Hands [ ]

8=Others……...

B3. What are the other symptoms that accompany the period pains?

1=Diarrhea [ ]

2=Nausea and Vomiting [ ]

3=Cramps [ ]

4=Head ache [ ]

5=Mood swings [ ]

B4. How long do the pains last?

1=Half a day [ ]

2=A whole day [ ]

3=More than two days [ ]

4=Others…….

B5. Have you experienced any side effects since you took the medication?

1=Yes [ ]

2=No [ ]

B6. If Yes, write the symptoms in the blank space below.

……

……

Section C: Dietary Information

C1**.**Record the following

1=Weight……

2**=**Height……

3**=**Body Mass Index……

C2. How often do you take breakfast?

1=Every day [ ]

2= Six times every week [ ]

3=Once a week [ ]

4=Never [ ]

C3. How many cups of coffee & or black tea & or chocolate do you consume everyday?

1=1 cup [ ]

2=2 cups [ ]

3=4 cups [ ]

4= I don't take any [ ]

C4. How many bottles of coca cola do you take every week?

1=1 bottle [ ]

2=3 bottles [ ]

3= none [ ]

C5. How many tea spoons of sugar do you add into your cup of beverages?

1=1 spoonful [ ]

2=2 spoonful [ ]

3=3 spoonful [ ]

4=None [ ]

C6. Towards your days for menses, do you often feel an urge to eat sweet things like chocolate, soda, juggery, sweets and the like?

1=Yes [ ]

2=No [ ]

C7. When in menstrual pain, are you restricted from doing your daily activities?

1=Yes [ ]

2=No [ ]

C8. If yes, what do you do instead?

1=I sleep [ ]

2=Am usually hospitalized [ ]

3=I take a walk [ ]

4=I ignore the pain and do what I enjoy most. [ ]

19. Write down briefly the school menu for the week in the table below, including things that you ate away from the dinning hall (for example milk tea,two slices of battered bread). Give a description of the food e.g. Boiled/fried eggs

DAYS OF THE WEEK	BREAK FAST	MID MORNING TEA	LUNCH	AFTER NOON TEA	SUPPER
Monday					
Tuesday					
Wednesday					
Thursday					
Friday					
Saturday					
Sunday					

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P.O. Box 43844, 00100
NAIROBI, KENYA
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Our Ref: H60/10303/08 **Date:** 16th November, 2009

The Chairman,
Ethical Review's Committee,
Kenya Medical Research Institute (KEMRI)
P.O. Box 54840,
NAIROBI

Dear Sir/Madam,

RE: RESEARCH AUTHORIZATION FOR MS. GOGI JULIE
- REG. NO. H60/10303/08

I write to introduce Ms. Gogi Julie who is a Postgraduate Student of this University. She is registered for an M.Sc degree programme in the **Department of Foods, Nutrition and Dietetics in the School of Applied Human Sciences.**

Ms. Gogi intends to conduct research for a thesis project entitled, *"Comparison between Magnesium Supplement and Ibuprofen (Brufen) as Treatment of Primary Dysmenorrhea among Adolescent Girls in Machakos District, Kenya."*

Any assistance given will be highly appreciated.

Yours faithfully,

KENYATTA UNIVERSITY
OFFICE OF DEAN
16 NOV 2010
GRADUATE SCHOOL
P.O. Box 43844 - 00100, NAIROBI

GEOFFREY K. KORIR
FOR: DEAN, GRADUATE SCHOOL

GKK/fwk

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KEMRI/RES/7/3/1 **January 14, 2011,**

TO: **JULIE GOGI (PRINCIPAL INVESTIGATOR)**
H60/10303/2008

THRO': **DEAN GRADUATE SCHOOL**
KENYATTA UNIVERSITY

RE: **NON-SSC PROTOCOL NO. 266 (*INITIAL SUBMISSION*): COMPARISON BETWEEN MAGNESIUM SUPPLEMENT AND IBUPROFEN (BRUFEN) AS A TREATMENT OF PRIMARY DYSMENORRHEA AMONG ADOLESCENT GIRLS IN MACHAKOS DISTRICT, KENYA.**

Make reference to your letter dated December 3, 2010 received on December 6, 2010. Thank you for your response to the issues raised by the Committee. This is to inform you that the issues raised during the 184th meeting of the KEMRI/ERC meeting held on 23rd November 2010, have been adequately addressed.

Due consideration has been given to ethical issues and the study is hereby granted approval for implementation effective this **14th day of January 2011,** for a period of twelve (12) months.

Please note that authorization to conduct this study will automatically expire on **13th January 2012.** If you plan to continue with data collection or analysis beyond this date, please submit an application for continuing approval to the ERC Secretariat by **15th September 2011**.

You are required to submit any amendments to this protocol and other information pertinent to human participation in this study to the ERC prior to initiation. You may embark on the study.

Yours sincerely,

RCKithinji

Caroline Kithinji,
FOR: SECRETARY,
KEMRI/NATIONAL ETHICS REVIEW COMMITTEE