FEMALE SEXUAL DYSFUNCTION AMONG WOMEN ON HORMONAL CONTRACEPTIVES COMPARED WITH THOSE ON NON-HORMONAL INTRAUTERINE CONTRACEPTIVE DEVICE AT THE KENYATTA NATIONAL HOSPITAL, 2019-2020

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DECLARATION

Student's declaration:

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

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DEDICATION

I dedicate this work to my family: Francis, Brilliant and Peace for their prayers, support and inspiration.

ABBREVIATIONS

ACOG	American College of Obstetricians and Gynecologists
COCs:	Combined Oral contraceptives
CPR:	Contraceptive prevalence rate
Cu-IUCD	Copper Intrauterine Contraceptive Device
DEPO	Depo Provera
FGM	Female Sexual Dysfunction
FSFI	Female Sexual Function Index
FSD:	Female sexual dysfunction
GBV	Gender Based Violence
IUD:	Intrauterine device
KDHS	Kenya Demographic Health Survey
KNH	Kenyatta National Hospital
POPs:	Progestin-only pills
SHBG:	Sex hormone-binding globulin
STI	Sexually Transmitted Infection
WHO:	World Health Organization.

OPERATIONAL DEFINITIONS

Contraception

Contraception has been defined, according to the American College of Obstetricians and Gynecologists (ACOG), as the prevention of pregnancy by interfering with the normal process of ovulation, fertilization, and implantation.

Hormonal Contraception

As pertains to this study, has been defined as the use of the following hormone containing methods to achieve contraception: progestin-only pills (POPs), progestin containing injectables and implants, and combined oral contraceptives (COCs) containing both estrogen and progestin.

Non-Hormonal Contraception

As pertains to this study, has been defined as the use of the non-hormone containing Copper Intrauterine Contraceptive Device (Cu-IUCD)

Contraceptive prevalence rate (CPR)

CPR has been defined by Kenya Demographic Health Survey (KDHS) as the percentage of women of reproductive age (15 — 49 years) using a modern contraceptive method.

Female Sexual Dysfunction (FSD)

As pertains to this study, Female Sexual Function Index (FSFI) score ≤ 26.55 is classified as FSD, and a score closer to ≤ 26.55 is described as being at risk of FSD.

World Health Organization WHO has defined Female Sexual dysfunction (FSD) as a disturbance in Sexual response resulting in disturbance in wellbeing and state of wellness, with poor quality of life.

Types of FSD

There are six major categories of FSD: sexual desire, arousal, lubrication, orgasmic, satisfaction and pain disorders. FSD is the presence of one or more of these disorders, based on FSFI score: a woman can be considered to have sexual dysfunction if she has one or more of these disorders.

Reproductive age

WHO has defined women of reproductive age as all women aged 15-49 years.

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ABSTRACT

Introduction: The Kenya Demographic Health Survey (KDHS), 2014 data, shows that most women of reproductive age (15-49 years) in Kenya are on hormonal contraceptive methods. Several studies have shown that hormonal contraceptives can predispose to female sexual dysfunction (FSD). This study, therefore, intended to establish the prevalence and types of FSD among women on hormonal contraceptives compared with those on non-hormonal IUCD in our set up, thus bring to attention the need to be aware of its presence for better management.

Objectives: To compare the prevalence and types of Female Sexual Dysfunction among women on hormonal contraceptives with those on non-hormonal IUCD, in the family planning clinic at the Kenyatta National Hospital, 2019-2020.

Study setting and design: A cross-sectional comparative study was conducted in the family planning clinic, at the Kenyatta National Hospital, Nairobi, Kenya.

Methodology: A total of 180 women on hormonal contraceptives and 180 on non-hormonal IUCD, of reproductive age (15 - 49 years old), were interviewed on several aspects of FSD including desire, arousal, pain, orgasm, pain and satisfaction disorders. The criterion of Female Sexual Dysfunction was evaluated by a Kiswahili translated version of the Female Sexual Function Index (FSFI). The questionnaire (FSFI) was used to assess sexual function for the previous 4 weeks, whereby, a score ≤ 26.55 was classified as FSD. Data on socio-demographic history was obtained. Data collection took three months, from December 2019 to February 2020. Data was analysed for prevalence with statistical significance set at $p<0.05$.

Results: Women on hormonal contraceptives had a higher prevalence of FSD compared with those on non-hormonal IUCD, 57.1% versus 40.0%, $p = 0.001$. The FSD scores of the four types (domains) of FSD (desire, arousal, lubrication, satisfaction) were significantly lower among women on hormonal contraceptives compared with those on non-hormonal IUCD, except in orgasm and pain domains where the FSD scores were statistically similar in the two groups. Women on hormonal contraceptives had two times increased odds of developing FSD, compared with their counterparts on non-hormonal IUCD, after adjusting for age, marital status, education and occupation: AOR 1.71 (95%CI: 1.05 to 2.80). Having tertiary level of education reduced the likelihood of having FSD by about 73%, after adjusting for age, marital status, occupation and contraceptive type: AOR 0.27 (95%CI: 0.13 to 0.57).

Conclusion: The prevalence of FSD was higher among women on hormonal contraceptives compared with those on non-hormonal IUCD. Women on hormonal contraceptives had two times increased odds of developing FSD, compared with their counterparts on non-hormonal IUCD, after adjusting for age, marital status, education and occupation. Women on hormonal contraceptives were more likely to suffer from the four types of FSD (desire, arousal, lubrication and satisfaction) compared with their counterparts on non-hormonal IUCD, except for orgasm and pain where the proportions were the same.

Recommendation: Routine individualized screening of FSD, in women, during hormonal contraceptive use, based on FSFI questionnaire protocol.

CHAPTER ONE: INTRODUCTION

1.1 Background Information

The female sexual response cycle has got the following phases: desire (libido), arousal (excitement), lubrication, orgasm, and resolution (satisfaction). Female sexual function is the ability to achieve successful sexual desire, arousal, lubrication, orgasm, and a feeling of satisfaction that promote a state of good health (1).

Female Sexual Dysfunction (FSD) is diagnosed when there is a problem in the sexual response. Therefore, there are six major types of FSD, based on the phases or components of sexual response cycle: desire, arousal, lubrication, orgasm, pain and satisfaction disorders. A diagnosis of FSD can be diagnosed if a woman presents with one or more of these six disorders (2).

The female sexual response phases or components are influenced by sex hormones; mainly estrogen, progesterone and testosterone. Since modern contraceptives mainly use synthetic sex hormonal formulations to prevent contraception, there is need to assess the impact that these have on female sexual functioning among reproductive women using them (3). The causes of FSD comprise hormonal and non-hormonal factors. Studies have shown that Hormonal contraceptives predispose to FSD (3).

The Kenya Demographic Health Survey (KDHS), 2014 data, has shown that the Contraceptive prevalence rate (CPR), which is the percentage of women of reproductive age (15 — 49 years) using a modern contraceptive method, is on the rise in Kenya, and that hormonal contraceptives are the most widely used modern method of contraception (4).

A study done, among female medical students in Germany, by Wallwiener M et al. (2010), has shown that the use of hormonal contraceptives predispose to FSD (5).

However, studies that have been done previously show that hormonal contraceptives have varying effects on female sexual function: some have shown strong association of hormonal contraceptives to FSD (6, 7), while other studies have shown no association (8, 9, 10, 11, 12).

Progesterone containing contraceptives have been shown to inhibit libido in women (13, 14): Studies done by Hassanin A.M. et al (2018) and Strufaldi et al., (2010) have shown that progestin-only contraceptives predispose to FSD (15, 16).

However, previous studies done by Hassanin A.M et al (2018), Koseoglu et al. (2016) and Enzlin et al. (2012) have shown that the use of non-hormonal intrauterine contraceptive devices (IUCDs) does not cause FSD (15, 17, 18).

Previous studies have reported varying prevalence of FSD, worldwide: a study done in Turkey recorded a prevalence of 48%, while a prevalence of FSD of 22% was reported in a Chilean study (19, 20). A study done in Morocco reported a prevalence of 27%, while a similar study in Brazil had a prevalence of 49% (21, 22). Previous studies done in Iran have recorded FSD prevalence ranging from 9% to 32% (24, 25). However, studies describing the prevalence of FSD from low income countries are few (25, 26). In Africa, the prevalence of FSD has been shown to be high, though there is need for more studies to fully describe it (25, 26). In Kenya, studies on the prevalence of FSD are limited (27).

The Female Sexual Function Index (FSFI) is the gold standard method for diagnosing FSD. The FSFI has six components (desire, arousal, lubrication, orgasm, satisfaction and pain) with 19 questions. The questionnaire (FSFI) assesses sexual function for the previous one month. A diagnosis of FSD is made when an FSFI score ≤ 26.55 is obtained. It is highly sensitive and specific and has been validated worldwide (28).

1.2 Prevalence of FSD

1.2.1 International studies

The prevalence of FSD has been shown to vary widely. In Europe, the prevalence ranges from 28% to 53% (29). In Asia, an average prevalence of 73% has been reported (30, 31), while in America, the prevalence ranges from 43% to 65% (32, 33, 34, 35). Based on several studies that have previously been done, an average of 40% of women will have some form of FSD in their lifetime (34, 35). Sakinci M et al (2016), in a Taiwan study, reported a prevalence of FSD of 41% in Cu-IUCD users (36). Panchalee T et al (2014), in a Thailand study, reported that the prevalence of FSD among the Cu-IUD users was 51% (37).

1.2.2 Regional Studies

High prevalence of FSD have been reported by different studies in Egypt: 68.9% by Elnashar et al. (38), 52.8% by Ibrahim et al. (39) and 76.9% by Hassanin et al**.** (15). In Morocco, a prevalence of 28% has been reported (21). In Nigeria, an FSD prevalence of 53.3% was reported by Nwagha, et al. (40) and a prevalence of 63% was reported by Fajewonyomi BA et al. (41). Rabab S. Hassan, et al. (2015), in an Egyptian study, showed that increasing the duration of the use of hormonal contraceptive increases the prevalence of FSD: the female who used hormonal contraception for 6 months up to one year had a prevalence of 54%, those who used for one to two years had a prevalence of 71%, while those who used for three years had a prevalence of 74%, and those who used for more than three years had a prevalence of 78% (42).

1.2.3 Local Studies

There is no specific study on prevalence of Female Sexual Dysfunction among women on hormonal contraception that has been carried out in Kenya. However, Geoffrey M. Likata Ungaya (2009) in his unpublished master's dissertation titled “The

Prevalence of Sexual Dysfunction among patients with Diabetes Mellitus attending the outpatient diabetes clinic at Kenyatta National Hospital" reported an FSD prevalence of 37% among women with type 2 diabetes mellitus, attending outpatient diabetes clinic (27).

CHAPTER TWO: LITERATURE REVIEW

A diagnosis of FSD is made when a full scale FSFI score ≤ 26.55 is obtained, and a score closer to ≤ 26.55 is described as being at risk of FSD. Hormonal contraceptives may predispose to FSD through various mechanisms (28).

2.1 Hormonal effect on sexual function

Estrogen, progesterone and testosterone are the three main female sex hormones. Estrogen is the most important hormone for sexual desire in women (43, 44, 45). During ovulation, levels of estrogen rise, resulting in increased sexual desire in women (43).

Several studies have shown that progesterone decreases sexual desire (46, 47, 48, 49).

Testosterone is produced in the female's adrenal glands and has been shown to increase sexual desire in women similarly to the high levels in men (43, 44).

2.2 Pathogenesis of hormonal contraceptive induced FSD

The pathogenesis of FSD in hormonal contraceptive methods is still not well known (50).

Hormonal balance is necessary for optimal sexual functioning (51).

Estradiol increases blood supply to the vagina, leading to vaginal lubrication (51, 52, 53) and improved sexual function (50). It follows, therefore, that when there is a reduction in estrogen levels, there will be decreased blood supply to the vagina, leading to reduced lubrication, and painful intercourse or dyspareunia.

One possible pathogenic mechanism, by which the use of hormonal contraceptive may cause FSD, could be explained as follows: sex hormone-binding globulins (SHBG), is a carrier glycoprotein for testosterone and estrogen. Estrogen increases levels of SHBG (7, 10, 55, 56, 57). Progestin may increase or decrease the effect of

estrogen on secretion of SHBG. Testosterone has a high binding capacity for SHBG. Thus, estrogen increases SBHG levels in serum. The SBHG binds the free testosterone, reducing its levels. Reduced levels of free testosterone may lead to reduced libido, hence FSD (58, 55, 56, 57, 59, 60).

Another possible mechanism for FSD is that the production of testosterone in the ovaries and adrenal glands may be inhibited, by the combined oral contraceptives, leading to FSD: Testosterone increases sexual desire (libido) in women, and therefore, reduced levels of the free testosterone may lead to FSD.

Progestins can also, through the neurotransmitter systems, such as the serotonin and aminobutyric acid systems, affect brain functioning. For example, during menstrual cycle, there is increased production of the metabolites of progesterone which predispose to premenstrual symptoms, such as being irritable, tense, depressed, and fatigued. Several studies have shown that using hormonal contraceptives that contain progesterone can lead to presentation with similar symptoms (5).

It has also been suggested that progestins may cause FSD, in some women, by antagonizing certain beneficial effects of estrogen (13, 14).

Studies done by A. M. Hassanin et al (2018) and Strufaldi et al., (2010) have shown that progestin-only contraceptives predispose to FSD (15, 16). Studies have also shown that Depo- Provera may cause weight gain, depression, vaginal atrophy and dyspareunia with decreased libido in some women (61, 62, 63).

2.3 Effect of hormonal contraceptives on female sexual function

The use of hormonal contraceptive methods may cause improved sexual functioning (as a result of the effects of estrogen) or may cause FSD (as a result of progestins)

(64). Therefore, combined oral contraceptives may reduce, increase or cause no change in sexual functioning in women (12, 44, 52, 65).

Progestogen-only contraceptives, such as depo-provera or implants containing progestogen have been shown to reduce sexual desire and function (66).

A Germany study, demonstrated that the use of hormonal contraceptive methods was associated with FSD (67).

A study done by Battaglia et al. (2011) showed that the use of COCs was associated with development of FSD (68).

However, studies by Wiebe E.R et al. (2011) and Burrows et al. (2012), reported no FSD among women using hormonal contraceptives (43, 50). A study by Kingsley and Salem (2010), also did not report any significant association of use of hormonal contraceptives to FSD (54). An Iranian study, by Hajian et al. (2015), did not show any significant association between FSD and the use of hormonal contraceptives (69).

Moreover, Ozgoli et al. (2015), did not report any significant association of use of Depo – provera to FSD (60).

Because of these unpredictable effects of hormonal contraceptives on female sexual functioning, some women tend to avoid using them, while some stop their use all together (70).

2.4 Diagnosis of FSD

The Female Sexual Function Index (FSFI) questionnaire is the gold standard for screening and diagnosing FSD, worldwide. It has six domains or components, corresponding to the six sexual response phases (desire, arousal, lubrication, orgasm, satisfaction, pain). It has 19 questions spread out into these six domains or areas. The

FSFI questionnaire is used to assess sexual function for the previous one month or 4weeks (28, 71).

The FSFI is highly, sensitive and specific, besides being cheap and easy to use and has been validated worldwide, including in Kenya (27, 28).

2.5 Schematic and narrative conceptual Framework

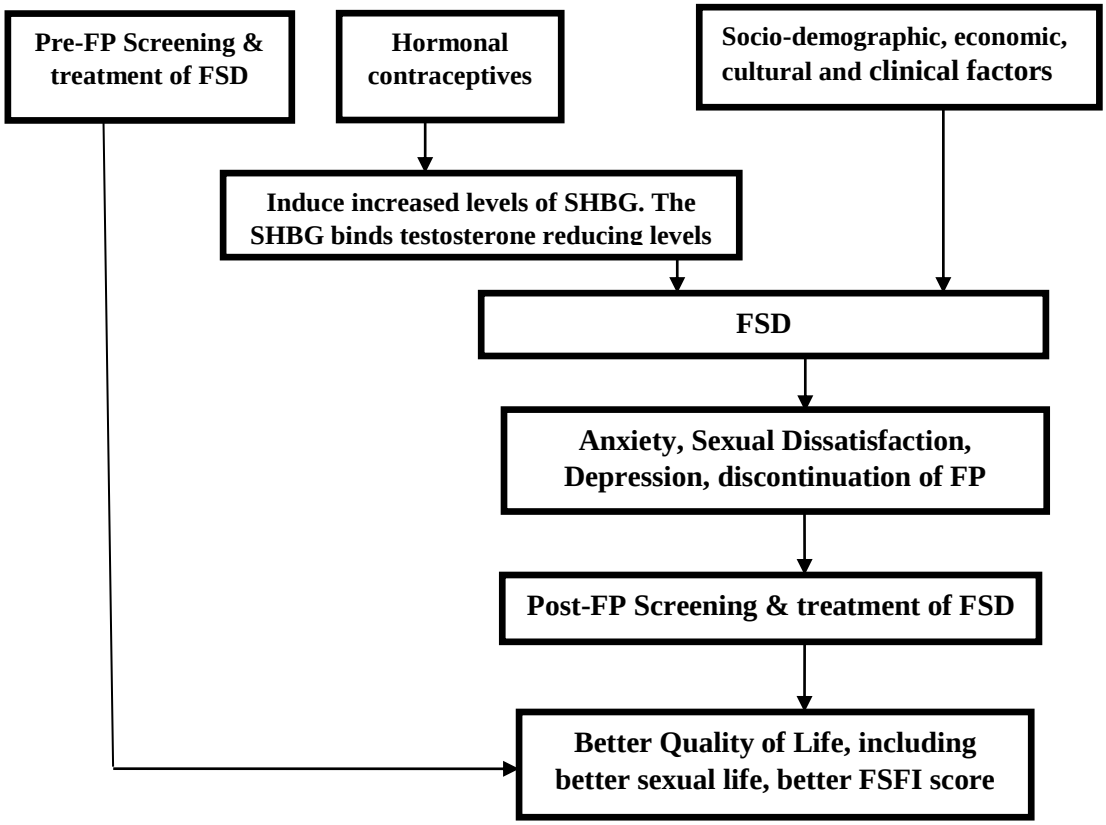

Figure 1: Schematic conceptual framework

The percentage of women of reproductive age (15 – 49 years) using a modern contraceptive method is on the rise in Kenya and the hormonal contraceptives are the most widely used modern method of contraception. The use of a contraceptive method can have a positive, negative or no effect on the female sexual functioning. A majority of the previous studies have shown that the use of non-hormonal Cu-IUCD does not predispose to FSD, as much as the hormonal contraceptives do. Other

factors, including socio-demographic, economic and medical, also do impact on FSD. The causal pathway of FSD is multifactorial. It has been shown that estrogen induces increase in the Sex Hormone Binding Globulin (SHBG). This is enhanced by progesterone. SHBG binds testosterone reducing levels hence reduced libido. Female Sexual Dysfunction predisposes the affected women to reduced quality of life characterized by anxiety, sexual dissatisfaction and depression. Because of these unpredictable effects of hormonal contraceptives on female sexual functioning, some women tend to avoid using them, while some stop their use all together. Pre- and post-FP screening and treatment of FSD promote better Quality Of Life (QOL), including better sexual life and better Female Sexual Functioning Index (FSFI) score. Therefore, this study seeks to determine the prevalence, types and factors associated with Female Sexual Dysfunction in women on hormonal contraceptives and non-hormonal Cu-IUCD methods at KNH, thus bring to attention the need to be aware of its presence when dealing with women of reproductive age for better management. This will provide evidence based data to promote sexual education and counselling to women using various types of contraceptive methods.

2.6 Problem Statement

Based on the KDHS 2014 data, modern contraceptive prevalence rate (CPR) is on the rise in Kenya and is projected to be 66 per cent by 2030 and 70 per cent by 2050, and that most women of reproductive age in Kenya are on hormonal contraceptive methods (4).Women should be counselled on the benefits and side-effects of every contraceptive method (72). Several studies have shown that using hormonal contraceptive methods may predispose to FSD (73). However, previous studies done by Hassanin A.M et al (2018), Koseoglu et al. (2016) and Enzlin et al. (2012) have

shown that the use of non-hormonal intrauterine contraceptive devices (IUCDs) does not cause FSD (15, 17, 18).

The pathogenic mechanism by which the use of hormonal contraceptives cause FSD is not yet fully known and, therefore, the effects cannot be generalized to all women (50).

The fear of developing FSD when a modern contraceptive method is used may cause a woman to stop usage or never use any method at all (70). On average, 40% of women, worldwide, are estimated to suffer from FSD (34, 35).

Previous studies have reported high prevalence of FSD in the US, Europe and Asia (34, 58, 74). For example, the following prevalence have been reported: USA (43 – 65%), Europe (28 – 53%), and Asia (46 – 67%) (29, 30, 31, 32, 33, 75).

High prevalence of FSD have been reported by different studies in Egypt: 68.9% by Elnashar et al. (38), 52.8% by Ibrahim et al. (39) and 76.9% by Hassanin et al. (15). In Morocco, a prevalence of 28% has been reported (21). In Nigeria, an FSD prevalence of 53.3% was reported by Nwagha, et al. (40) and a prevalence of 63% was reported by Fajewonyomi BA et al. (41).

There is no specific study on prevalence of Female Sexual Dysfunction among women on hormonal contraception that has been carried out at the KNH. However, Geoffrey M. Likata Ungaya (2009) in his unpublished master's dissertation titled “The Prevalence of Sexual Dysfunction among patients with Diabetes Mellitus attending the outpatient diabetes clinic at Kenyatta National Hospital,” reported an FSD prevalence of 36.6% among women with diabetes mellitus attending outpatient diabetes clinic (27).

2.7 Study Justification

The side-effects of a contraceptive method on sexual functioning is a very important factor when deciding upon the method of contraception to use by women (69). Use of hormonal contraceptives may bring about sexual dysfunction as one of their complications, whose psychological effects on the affected person could lead to impaired quality of life in terms of dissatisfaction with the partner, anxiety and low self-esteem in life as a result of impaired sexual function/performance. The study, therefore, intends to establish the prevalence of sexual dysfunction in our set up, thus bring to attention the need to be aware of its presence when dealing with premenopausal women, using hormonal contraceptives, for their better management. Previous studies done by Hassanin A.M et al (2018), Koseoglu et al. (2016) and Enzlin et al. (2012) have shown that the use of non-hormonal intrauterine contraceptive devices (IUCDs) does not cause FSD (15, 17, 18).

There is paucity of data on the prevalence and types of FSD in Kenya. Previous studies by Burrows, Basha and Goldstein have recommended that further studies on the side effects of hormonal contraceptive on female sexual functioning need to be done **(**43). The data obtained will form a basis for informed screening and diagnosis of FSD in women on hormonal contraceptives.

FSD can easily and cheaply be screened and diagnosed using the FSFI, which is the gold standard method for diagnosing FSD, and has been validated worldwide, including in Kenya (28).

2.8 Research Question

What is the impact of hormonal contraceptives and non-hormonal IUCD on the Sexual function of women in the FP clinic at KNH?

2.9 Study Objectives

2.9.1 Broad objective

To compare the prevalence and types of Female Sexual Dysfunction among women on hormonal contraceptives with those on non-hormonal IUCD, in the family planning clinic at the Kenyatta National Hospital, 2019-2020.

2.9.2 Specific objectives

Among women attending family planning clinic at KNH, 2019-2020, to:

1. Compare the prevalence of Female Sexual Dysfunction in those on hormonal contraceptives with those on non-hormonal IUCD.
2. Compare the types of Female Sexual Dysfunction in those on hormonal contraceptives with those on non-hormonal IUCD.
3. Assess whether the type of contraception used is associated with female sexual dysfunction, adjusted for socio-demographic, economic, cultural and clinical factors.

CHAPTER THREE: METHODOLOGY

3.1 Study Design:

This was a cross sectional study design on female sexual dysfunction among women on hormonal contraceptives compared with those on non-hormonal contraception at Kenyatta national hospital, 2019-2020. This design enabled the determination of the prevalence of FSD and the associated factors, but not the causal factors. The design was also convenient for the clients since all information on exposure and outcome (FSD) was collected at one point in time.

3.2 Study Setting:

The study was conducted at the Family planning clinic is at the Kenyatta National Hospital (KNH). KNH is the largest and oldest teaching and referral hospital in Kenya. It was founded in 1901, and is located about 3.5km west of the Nairobi city's central business district, and serves as the teaching hospital of the College of Health Sciences at the University of Nairobi. It offers both general medical and surgical services, with several outpatient specialist clinics including the family planning clinic. The Family Planning Clinic at KNH has the following staff: one health information officer, 2 subordinate staff, one HIV testing and counselling staff, and six trained nurses in reproductive health (family planning). The registrars and consultants from the department of Obstetrics and Gynaecology are also involved in the client care, as part of the training. The clinic also houses the paediatric immunization clinic. The services provided are very affordable and it is mostly a walk-in clinic and there is no requirement for referral for a client to be attended to. The clients are mostly from Nairobi, as self-referrals, or from wards after discharge, and from Post Natal Clinic, only a minority is referrals.

The Family Planning clinic in KNH has approximately 730 clients on family planning methods, distributed as follows:

Women on Non-hormonal Cu-IUCD contraceptive: The women on non-hormonal IUCD in the Family Planning Clinic at KNH were about 211, as at August, 2019.

Women on hormonal contraceptives: The women on hormonal contraceptives in the Family Planning clinic at KNH were about 520, as at August, 2019.

COCs (192) + POPs (104) + Jadelle (69) + Implanon (84) + Injectables (65) = 520

Client flow in the KNH FP clinic

Once a new client comes to the family planning clinic at KNH, she goes to the health information office, where she is issued with a family planning card, and her socio-demographic data is filled. Then, the client goes to the attending nurse, specifically trained in family planning. After clinical examination and counselling, the client is put on the best family planning method based on her clinical status and preference. The client is then allowed home, to come again for review after three months (for those put on IUCD, COCs, POPs) or after one week (for those put on implanon or Jadelle). The clients are not routinely screened for Female Sexual Functioning in the Family Planning Clinic. The clients pay for the services at the different cash points at the KNH.

Figure 2 below describes the client flow in the family planning clinic. The clients pay for the services at the different cash points at the KNH.

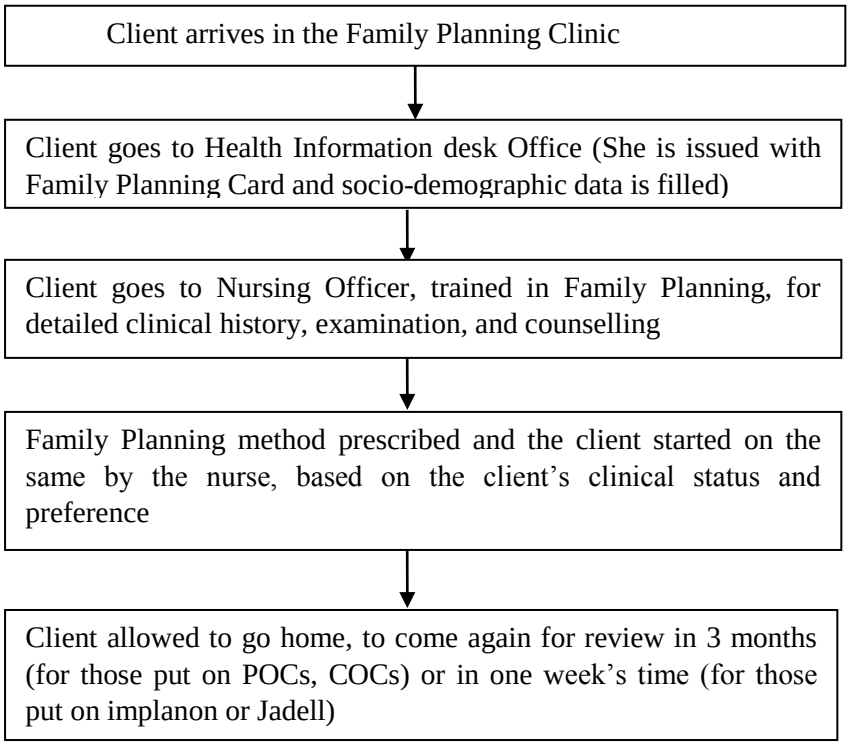

Figure 2: Algorithm of Client flow in the Family Planning Clinic

An average number of 10 clients (new and old clients for review) is seen in the Family Planning Clinic at KNH every working day.

The study area was chosen and noted to be suitable because the results of the study can be generalized to all women on hormonal contraceptives and non-hormonal IUCD, in Nairobi, its environs and the country at large, they represent the target population because, as a referral hospital, K.N.H attends to patients from Nairobi and other parts of the country (76).

3.3 Study population:

The study population comprised women on hormonal contraceptives and non-hormonal IUCD for the previous four weeks.

3.4 Target population:

The target population comprised women aged 15-49 years on hormonal contraceptives and non-hormonal (Cu-IUCD) contraceptives.

3.5 Eligibility Criteria

3.5.1 Inclusion Criteria

1. Women aged 15 to 49 years on hormonal contraception and non-hormonal Cu-IUCD methods for the last 4 weeks.
2. Women on follow up in the Family Planning (FP) clinic at KNH (2019-2020)

3.5.2 Exclusion Criteria

1. Women with known causes of FSD- such as Diabetes Mellitus, Pelvic Inflammatory Disease (PID), Urinary Tract Infection (UTI) etc., medications (such as anti-psychotics)
2. Women who couldn't have sex for other reasons like spouse was away in the last 4 weeks.
3. Women on non-hormonal contraception methods, other than Cu-IUCD: this is because in the family planning clinic at KNH, the only women on non-hormonal method being followed up were those on Cu-IUCD.

3.6 Sampling method:

In the hormonal contraceptive using group of participants, stratified random sampling technique was used to determine the number of participants that were recruited from each stratum (Combined oral contraceptives, progestin only pills, Jadell, implanon and Depo). Then, systematic random sampling was applied within each stratum, whereby every second participant, meeting the inclusion criteria, was enrolled into the study.

In the non-hormonal (IUCD) contraception group, systematic random sampling was used whereby every second participant, meeting the inclusion criteria, was enrolled into the study. Every second patient was chosen so that the sample size could be adequately achieved. This was to ensure equal chance for all subjects that ware available to be included in the study, so that the sample size was a better representation of the entire population of women on hormonal contraceptives and non-hormonal Cu-IUCD.

3.7 Sample Size

A minimum of 360 women of reproductive age on contraception (both hormonal and non-hormonal) were enrolled into the study. This sample size, with 180 women of reproductive age on non-hormonal Cu-IUCD and 180 on hormonal contraceptives was powered to 80% to detect the difference in the prevalence of Female Sexual Dysfunction between the reproductive women on non-hormonal Cu-IUCD and those on hormonal contraceptives.

Prevalence of FSD for women on hormonal contraceptives was based on the findings reported by Rabab S. Hassan, et al. (2015): in that study, as the duration of the use of the hormonal contraceptives increased, the FSD also increased, as follows: The women who used hormonal contraceptive for 6 months up to one year had an FSD prevalence of 54%, those who used for one year had a prevalence of 71%, those who used for three years had a prevalence of 74% and those who used for more than three years had a prevalence of 78 (42). Calculating the average prevalence of FSD for this study gives (54% +71% +74% + 78%/4) = 69%

Prevalence of FSD for women on IUCD was based on the average prevalence of the two studies from Taiwan and Thailand: Sakinci M et al (2016), in a Taiwan study, had a prevalence of FSD of 41% among the Cu-IUCD users (36).

Panchalee T et al (2014), in a Thailand study, reported that the prevalence of sexual dysfunction in Cu-IUD users was 51%. (37).

The average prevalence between the Taiwan and Thailand studies gives a prevalence of (41 + 51)/2 = 46%

Therefore, in this study we chose the prevalence of FSD in women of reproductive age on hormonal contraceptives as 69% and in women of reproductive age on IUCD as 46%.

Determining sample size for objective 1: Hulley S et al. (2007) formula (77) for comparing two proportions was used to determine the sample size for the women of reproductive age using hormonal contraception group and the non-hormonal contraception group, as follows:

$$N = \frac{\left(Z_{1-\alpha/2} \times \sqrt{\frac{(p1 + p2)x\,(2 - p1 - p2)}{2a}} + Z_{1-\alpha/2} \times \sqrt{p1(1-p1) + p2(1-p2)} \right)^2}{(p1 - p2)^2}$$

$$N = \frac{\left(1.96 \times \sqrt{\frac{(0.46 + 0.69)x\,(2 - 0.46 - 0.69)}{2a}} + 0.84 \times \sqrt{0.46(1-0.46) + 0.69(1-0.69)} \right)^2}{(0.46 - 0.69)^2}$$

N=288 (144, 144)

For women on IUCD, we needed to enroll at least 144participants.

For women on hormonal contraceptives, we also needed to enroll at least 144 participants.

Where p_1 is the proportion of FSD among women on non-hormonal Cu-IUCD contraceptive (p1=45.5%) and p_2 is the proportion of FSD among women on hormonal contraceptives (p2=69%).

P1= 45.5%= 0.455= 0.46,

P2= 69%= 0.69

$z_{1-\alpha/2}$ is the $100(1-\alpha/2)$ percentile of the standard normal distribution under type I error while $z_{1-\beta}$ is the $100(1-\beta)$ percentile of the standard normal distribution under type II error.

$p_1 - p_2$ gives the effect size.

For women on Cu-IUCD we needed to enroll at least 144 participants:

Correcting for a potential non-response rate of 20% (r =0.2) gave us:

$\frac{n}{(1-r)} = \frac{144}{(1-0.2)}$ = 180 participants.

For women on hormonal contraceptives we needed to enroll at least 144 participants:

Correcting for a potential non-response rate of 20% (r =0.2) gave us:

$\frac{n}{(1-r)} = \frac{144}{(1-0.2)}$ = 180 participants.

Thus, the total sample size was (180+180) = 360

Determining sample size for objective 2: Peduzzi et al. (1996) formula (78) for calculating sample size for logistic regression was used as follows:

N = 10k/p

Where,

N = sample size,

K = number of independent variables,

P = prevalence (from previous study)

There are 6 types of FSD (sexual desire, arousal, lubrication, orgasm, satisfaction and pain): therefore, k = 6

Based on prevalence of FSD for women on IUCD of 0.46 (46%), as illustrated above, p = 0.46

Therefore, sample size, $N = \frac{10K}{p} = \frac{10\,(6)}{0.46} = \frac{60}{0.46} = 130$

Based on prevalence of FSD for women on hormonal contraceptives of 0.69 (69%), as illustrated above, p = 0.69

$N = \frac{10K}{p}$, $N = \frac{10\,(6)}{0.69} = \frac{60}{0.69} = 87$

Since, the sample size calculated by Hulley S et al. (2007) formula for comparing the two proportions, in objective 1 above was the highest (360), we used the same as the overall sample size for this study.

Determining sample size for objective 3: Peduzzi et al. (1996) formula (78) for calculating sample size for logistic regression was used as follows:

N = 10k/p

Where,

N = sample size,

K = number of independent variables,

P = prevalence (from previous study)

There were 10 independent variables (possible factors associated with FSD):

therefore, k = 10

(Age, marital status, parity, educational level, religion, occupation, Family planning method, sexual problem, medical condition)

Based on prevalence of FSD for women on IUCD of 0.46 (46%), as illustrated above, p = 0.46

$N = \frac{10K}{p}$, $N = \frac{10\,(10)}{0.46} = \frac{100}{0.46} = 217$

Based on prevalence of FSD for women on hormonal contraceptives of 0.69 (69%), as illustrated above, p = 0.69

$$N = \frac{10K}{p}, \quad N = \frac{10\ (10)}{0.69} = \frac{100}{0.69} = 115$$

Since, the sample size (of 360) calculated by Hulley S et al. (2007) formula (77) for comparing the two proportions, in objective 1 above was the highest, it was used as the overall sample size for this study.

All women of reproductive age on contraception were recruited. The Family Planning clinic in KNH has approximately 730 clients on family planning methods, distributed as follows:

Table 1: Types and numbers of contraceptives

Contraceptive method	Number of users
IUCD	211
COCs	192
POPs	104
Jadelle	69
Implanon	84
Injectables (Depo)	71
Total	730

3.8 Sampling Technique

Stratified random sampling technique was used to select participants using hormonal contraceptives in each stratum (combined oral contraceptives, progestin only pills, Jadelle, Implanon and injectables). Then, systematic random sampling was applied within each stratum, whereby every second participant, meeting the inclusion criteria, was enrolled into the study.

Systematic random sampling technique with a sampling interval of 2 was used to select the participants using non hormonal contraceptive, for the study as described below.

Women on Non-hormonal Cu-IUCD contraceptive

Systematic random sampling technique was used to select the participants using non hormonal contraceptive. The women on non-hormonal Cu-IUCD were enrolled from the Family Planning Clinic in KNH. The population size of women on non-hormonal Cu-IUCD was 211.

Based on the population size and the sample size the sampling interval (k) = 211 / 114 = 2. Therefore, in this group we sampled every second client.

Women on hormonal contraceptives

Stratified random sampling technique was used to select participants using hormonal contraceptive. The women on hormonal contraceptives were also enrolled from the Family Planning clinic in KNH. The population size of women on hormonal contraceptives was 520.

COCs (192) + POPs (104) + Jadelle (69) + Implanon (84) + Depo (71) = 520

Table 2: Sample size per stratum of participants on hormonal contraceptives, in the FP clinic at KNH, based on stratified random technique, 2019-2020

Hormonal contraceptive type	Percentage of target population on each hormonal contraceptive type	Number of participants per stratum of hormonal contraceptives to be recruited
COCs	$\frac{192 \times 100}{520} = 37\%$	$\frac{37 \times 180}{100} = 67$
POPs	$\frac{104 \times 100}{520} = 20\%$	$\frac{20 \times 180}{100} = 36$
Jadelle	$\frac{69 \times 100}{520} = 13\%$	$\frac{13 \times 180}{100} = 23$
Implanon	$\frac{84 \times 100}{520} = 16\%$	$\frac{16 \times 180}{100} = 29$
Injectables	$\frac{71 \times 100}{520} = 14\%$	$\frac{14 \times 180}{100} = 25$
Total sample size	100%	180

Since we had a sample size of 180, therefore, the numbers of participants on different hormonal contraceptives ware recruited per stratum as shown in table 2 above.

Systematic random sampling was applied within each stratum, whereby every second participant, meeting the inclusion criteria, was enrolled into the study.

3.9 Study Procedure

Subjects were recruited in the Family Planning Clinic in KNH. Those who did not meet the eligibility criteria were excluded. Participants who met the criteria were approached and requested to participate in the study. Figure 2 below shows a summary of the study flow algorithm. Recruitment of women on hormonal contraceptives and those on non-hormonal IUCD were done in the Family Planning Clinic at the waiting bay after they had been seen by the clinicians/nurses.

The study interviews were done in the Family planning clinic. The purpose of the study and the potential benefits were explained to the participants individually in a language they understood and all their questions were answered. Those who met the inclusion criteria and consented to participate in the study were enrolled after signing informed consent forms (Appendix I and II).

The participants were then recruited either into the hormonal contraceptive (exposed) arm or non-hormonal contraceptive Cu-IUCD (comparison) study arm. The two study arms had equal number of participants (180 in non-hormonal Cu-IUCD contraception group and 180 in hormonal contraceptives group). The subjects on hormonal contraceptives and those on non-hormonal Cu-IUCD contraceptive were matched for age (±5years). The age was self-reported and confirmed from the documents (clinical data and/or national identity card). A predesigned matching matrix was used to match for age (±5). Recruitment was done until the desired sample size was achieved in each of the two study arms.

A standardized questionnaire was used to collect bio-social and clinical data (Appendix III-English version and Appendix VII-Kiswahili version and the corresponding collation table 9).

FSFI questionnaire tool was used to collect sexual dysfunction data (Appendix IV-English version and Appendix VIII-Kiswahili version with corresponding collation table 10).

3.10 Study Flow

After recruitment, the participants' socio-demographic characteristics and clinical data were collected by the study questionnaire (English version-Appendix III and the Kiswahili version-Appendix VII). Subsequently, the participants were taken through the Female Sexual Function Index (FSFI), a brief 19-item questionnaire: a multidimensional self-report instrument for assessing the key dimensions of sexual function in women (English version-Appendix IV and the Kiswahili version-Appendix VIII). The algorithm for the study procedure is summarized in Figure 2 below.

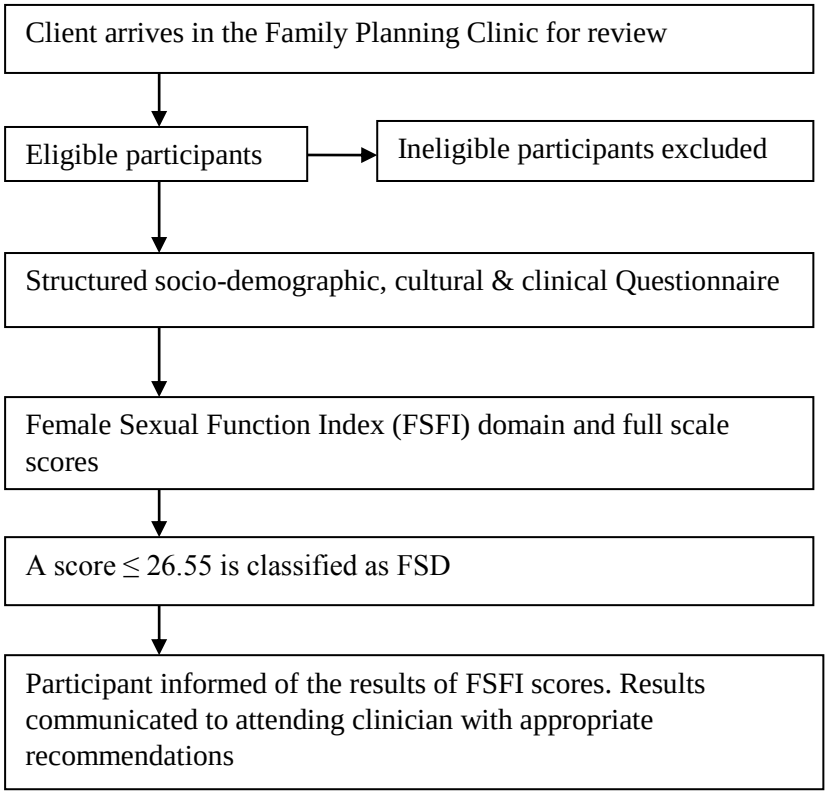

Figure 3: Algorithm of study Flow Chart

3.11 Study tool:

A structured socio-demographic characteristic of the respondents was incorporated into the Female Sexual Function Index (FSFI) questionnaire. The FSFI is a 19‑item questionnaire, which was developed as a brief, multidimensional self‑report

instrument for assessing the fundamental dimensions of sexual function in women in the preceding 4 weeks. It provides scores on six domains of sexual function (desire, arousal, lubrication, orgasm, satisfaction, and pain) as well as a total score (Appendix B). Scores were given to individual participants in the six domains (desire, arousal, lubrication, orgasm, satisfaction, pain). The score ranges from 0 to 6. Within the individual domains, a domain score of zero indicates that the subject reported having no sexual activity during the past month. For the individual domain scores, the individual items that comprise the domain were added and the sum was multiplied by the domain factor. The six domain scores were added to obtain the full scale score. A score ≤ 26.55 was classified as FSD, while a score closer to ≤ 26.55 was described as being at risk of FSD (Appendix B).

Validation: The FSFI has been validated on clinically diagnosed samples of women with female sexual arousal disorder, female orgasmic disorder, and hypoactive sexual desire disorder. The FSFI questionnaire tool has been validated worldwide in both developed and developing countries including, Egypt (Ahmed Mohamed Hassanin A.M et al., 2018) and Nigeria (Nwagha UI et al., 2014) among others (15, 40).The same tool has been validated in our diabetic female and male African population in KNH by Geoffrey M. Likata Ungaya, in 2009, in his unpublished master's dissertation titled: "The prevalence of sexual dysfunction among patients with diabetes mellitus attending the outpatient diabetic clinic at Kenyatta national hospital (27)."

A set of pretested structured questionnaire, designed by the principal researcher, was used for collecting information. The questionnaire contained both open- and close-ended questions. The interviewers were the principal researcher and the final-year female medical students who had been properly trained on the sensitive nature of the

study. This study was carried out in the family planning clinic at KNH. Once the potential participants had been seen in the FP clinic by a clinician, they were directed to a separate private room in the same clinic, for potential recruitment of eligible participants and interviews

A female medical student privately interviewed each respondent. Female Sexual Dysfunction in this study was defined as women of reproductive age (15-49 years), who experienced any of the disorders associated with desire, arousal, orgasm, and painful sex (dyspareunia and vaginismus) and lack of satisfaction in four weeks preceding the study. A pilot study was done in a separate hospital setting (in the family planning clinic, at the Mbagathi hospital). The questionnaire tools were found to be relevant and no modifications were made in them before commencement of the study. Thirty participants were recruited in the pilot study. This was based on the evidence by Isaac and Michael (1995) who have suggested 10 – 30 participants for pilot study (79). Hill (1998) has also suggested 10 to 30 participants (80). Section II of the questionnaire was used to elicit information on the sociodemographic background of the respondents. Section III was used to investigate their sexual history with respect to sexual desire, arousal, orgasm, sexual pain disorders, emotional state, and the primary problems which brought them to hospital. The information was collated and fed into a personal password protected computer accessible only to the principal researcher.

3.12 DATA VARIABLES

3.12.1 Primary outcome variable

1. Female Sexual Dysfunction (FSD): Defined as having FSFI full scale score ≤26.55

3.12.2 Secondary data variables

1. Age
2. Marital status
3. Education
4. Occupation
5. Religion
6. Female Genital Mutilation
7. Gender Based Violence
8. Sexually Transmitted Infections

3.13 Data management

Data was collected using standardized questionnaires (Appendix III, IV, VII, and VIII). Data was cleaned and then entered into Excel and analysed using the STATA version 15 SE. with statistical significance set at $p<0.05$.

Patient data was de-identified (the name and hospital number of the patient were excluded, and only an assigned study number was used) and entered into a research database. Data was stored into one master database matched by the participant's unique identification number and void of personal identifiers. All subsequent data analyses used this dataset to protect the confidentiality of participants.

3.14 Data analysis

Data was analyzed using STATA 15.

Before analysis, the variables were checked for outliers, inconsistencies, missing data and distribution. Visual inspection of all continuous variables using scatter plots, box plots or histograms was done to identify outliers and distribution of the data. Some of the values in the categorical variables were grouped especially where the subgroups had small numbers.

Descriptive analysis was carried out to provide a description of the population through means (standard deviations) or medians (interquartile range) and frequencies (percentages) and presented in the tables shown in the results section. Chi square and student T test were used to test for statistical significance. Wilcoxon rank sum test was for non-normally distributed continuous variables while Fishers' exact test was where frequencies were small.

Inferential bivariate analysis was carried out to determine whether the observed differences between the hormonal and non-hormonal contraceptive use was due to chance.

Objective 1: Proportions were calculated for FSD in Hormonal and non-Hormonal users then compared using chi square for statistical significance.

Objective 2: Median and interquartile ranges were calculated for each of the FSFI domains and compared for significance by contraceptive use using Wilcoxon rank sum test.

Objective 3: Bivariate and multivariate logistic regression were carried out and ORs were used to establish associations**.** Simple logistic regression was used to compare association between contraceptive use and FSD, crude odds ratio with 95% confidence intervals have been presented. Each of the covariates was checked for association with Contraceptive use and FSD. Factors found to be significantly related to both Contraceptive use and FSD were included in the final logistic regression model.

3.15 Ethical Considerations

Prior to initiating research study, research proposal was submitted for acknowledgement by the department of Obstetrics and Gynecology, University of

Nairobi, Kenya, and approval by the Ethics and Research Committee (ERC). A written permission was also sought from the KNH administration.

Patients who were recruited for the study were informed that participation was voluntary and that they could withdraw from the study at any point. The purpose of the study was explained at an appropriate educational level to ensure understanding and all participants were required to sign a written consent form delineating the objectives of the study and their rights.

Participants were informed that the project did not carry monetary benefits and no cost would be incurred by them.

The participants were also informed that they would receive free counselling and health education on FSD by the principal researcher, as pertains to FSD. Where more counselling sessions were required, she would be referred to a qualified registered counsellor at the KNH. She would also be referred to a hospital for care and support where necessary. The participants who were found to have medical conditions that predispose to FSD, such as urinary tract infections and pelvic inflammatory disease were to be managed accordingly: the principal investigator would have prescribed appropriate work up and treatment and then referred for follow up reviews in the usual patient follow up mechanisms for out- patients in KNH- either to Accident and Emergency or to Gynaecological Outpatient Clinic (GOPC).

Patient data was de-identified (the name and hospital number of the patient were excluded, and only an assigned study number was used) and entered into a research database. Data was stored into one master database matched by the participant's unique identification number and void of personal identifiers. All subsequent data analyses used this dataset to protect the confidentiality of participants. The principal

investigator and research assistants upheld the highest level of confidentiality and privacy for all participants.

3.16 Study Strengths

1. This was a comparative study comparing prevalence of Female Sexual Dysfunction between women of reproductive age on hormonal contraceptives and those on non-hormonal Cu-IUCD contraceptive method for better understanding of the effect of hormonal contraception on the female sexual functioning.
2. The study was powered to 80% to detect the difference in the prevalence of Female Sexual Dysfunction between the reproductive women on non-hormonal Cu-IUCD and those on hormonal contraceptives.
3. The Female Sexual Function Index (FSFI) which is the gold standard method to determine female sexual functioning was used in this study. FSFI is highly specific and sensitive to diagnose Female Sexual Dysfunction and has been validated worldwide, including Kenya. It is cheap and simple to use.
4. The study employed systematic random sampling and stratified random sampling techniques to reduce bias
5. The study was matched for age (±5): women on hormonal versus those on non-hormonal contraceptives to reduce bias
6. The study had a large sample size to enable generalization of results
7. The questionnaires were uniformly interviewer administered to reduce bias.

3.17 Study Limitations

This was a cross sectional study design and as such showed the association and not causal effect

This study did not evaluate sexual function before FP method. However, this has been overcome by having two comparison groups.

CHAPTER FOUR: RESULTS

4.0 Introduction

The results have been tailored to answer the three objectives of this study. For objective one the proportions were calculated for FSD in Hormonal and non-Hormonal users then compared using chi square for statistical significance. For objective two, the median and interquartile ranges were calculated for each of the FSFI domains and compared for significance by contraceptive use using Wilcoxon rank sum test. For objective three, bivariate and multivariate logistic regression were carried out and Odds Ratios were used to establish associations**.**

4.1 Screening and recruitment of participants on contraception at KNH

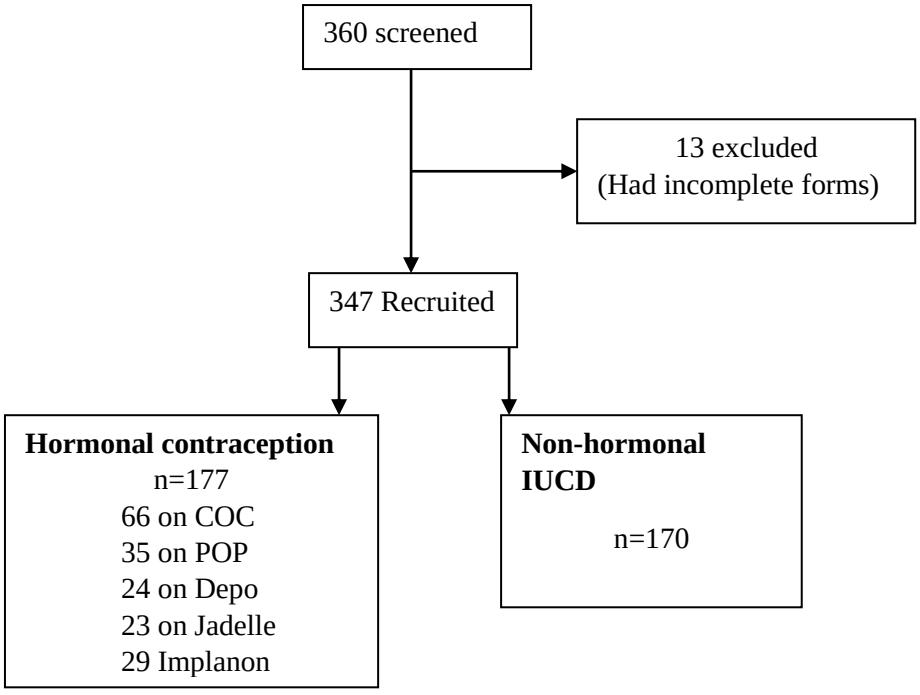

Figure 4: Recruitment Schema of women on non-hormonal IUCD and hormonal contraceptives in the FP clinic at KNH.

A total of 360 participants (180 women on hormonal contraceptives and 180 on non-hormonal IUCD) were screened for the study between December 2019 and February

2020. Of these, 347 (177 on hormonal contraceptives and 170 on non-hormonal IUCD) fulfilled the inclusion criteria, and were recruited.

Table 3: Baseline factors/characteristics of women on non-hormonal IUCD compared with those on hormonal contraceptives in the FP clinic at KNH, 2019-2020

Baseline Characteristics		**Non-Hormonal IUCD N = 170**	**Hormonal contraceptives n = 177**	**OR 95% CI**	**P value**
Age	Mean (±2SD)	34.3 (6.5)	30.6 (6.2)	0.91(0.88 to 0.95)	0.001
Age	≤30 years	54 (31.8%)	97 (54.8%)	1	
	> 30 years	116 (68.2%)	80 (45.2%)	0.38 (0.24 to 0.59)	0.001
Marital status	Single	14 (8.2%)	25 (14.1%)	1	
	Married	147 (86.5%)	147 (83.1%)	0.56 (0.28 to 1.12)	0.128
	Div/widowed/separated	9 (5.3%)	5 (2.8%)	0.31 (0.09 to1.11	0.125
Education	Primary	25 (14.7%)	37 (20.9%)	1	
	Secondary	45 (26.5%)	68 (38.4%)	1.38 (0.80 to 2.41)	0.075
	Tertiary	100 (58.8%)	72 (40.7%)	2.4 (1.21 to 4.75)	0.003
Occupation	Professional	47 (27.7%)	31 (17.5%)	1	
	Business	83 (48.8%)	76 (42.9%)	1.38 (0.80 to 2.41)	0.24
	Skilled	24 (14.1%)	38 (21.5%)	2.40 (1.21 to 4.75)	0.01
	Learners	16 (9.4%)	32 (18.1%)	3.03 (1.42 to 6.43)	0.004
Religion	Catholic	46 (27.1%)	52 (29.4%)	1	
	Protestant	114 (67.1%)	111 (62.7%)	0.86 (0.53 to 1.38)	0.54
	Others	10 (5.8%)	14 (7.9%)	1.23 (0.50 to 3.06)	0.64
FGM	No	165 (97.1%)	173 (97.7%)	1	
	Yes	5 (2.9%)	4 (2.3%)	0.76 (0.20 to 2.89)	0.69
GBV	No	169 (99.4%)	172 (97.2%)	1	
	Yes	1 (0.6%)	5 (2.8%)	4.91(0.56 to 42.49)	0.14
STIs	No	169 (99.4%)	174 (98.3%)	1	
	Yes	1 (0.6%)	3 (1.7%)	2.91 (0.30 to28.29)	0.62

Older women were more likely to be on non-hormonal IUCD rather than being on hormonal contraceptives: in fact, women who were more than 30 years old had 62% reduced likelihood of being on hormonal contraceptives

Women who had tertiary level of education had two times increased likelihood of being on non-hormonal IUCD, compared with those who had primary level of education.

The women who were skilled and those who were learners were more likely to be on hormonal contraceptives compared with those who were professional.

The differences in the proportions of women among those who were on non-hormonal IUCD compared with those who were on hormonal contraceptives were statistically insignificant, in terms of marital status, religion, and previous history of FGM, GBV and STIs.

Table 4: Prevalence of FSD among women on non-hormonal IUCD compared with those on hormonal contraceptives, in the FP clinic at KNH, 2019-2020

Presence of FSD	Non-hormonal IUCD n = 170	Hormonal contraceptives n = 177	P value
No	102 (60.0%)	76 (42.9%)	0.001[c]
Yes	68 (40.0%)	101 (57.1%)	

FSD – Female Sexual Dysfunction; FSFI – Female Sexual Function Index; [c] Pearson's Chi Square [t] Student t test, FSD = FSFI Full Scale score ≤ 26.55

Prevalence of FSD among women using Hormonal contraceptive was (177/347) 57.0% (95% CI 49.4 to 64.5%)

Prevalence of FSD among women using non-Hormonal contraceptive was (170/347) 40.0% (95% CI 32.6 to 47.8%)

The prevalence of FSD was significantly higher among the women on hormonal contraceptives compared with those on non-hormonal IUCD, 57.1% versus 40.0%, p = 0.001[c]

Table 5: The types of Female Sexual Dysfunction in women on non-hormonal IUCD compared with those on hormonal contraceptives in FP clinic at KNH, 2019-2020

TYPES OF FSD	**Median (IQR)**	**Non-Hormonal IUCD**	**Hormonal contraceptives**	**P value**
Desire	**3.5 (0.6)**	**3.6 (0.6)**	**3.4(0.6)**	**0.003**
Arousal	**3.9 (0.9)**	**3.9 (1.2)**	**3.6 (0.9)**	**0.002**
Lubrication	**4.8 (1.5)**	**4.8 (1.2)**	**4.5 (1.2)**	**0.001**
Orgasm	**4.8 (1.2)**	**4.8 (1.2)**	**4.4 (1.6)**	**0.102**
Satisfaction	**4.8 (1.6)**	**5.2 (1.2)**	**4.8 (2)**	**0.002**
Pain	**5.2 (2)**	**5.2 (2)**	**5.2 (2)**	**0.93**
Full score	**26.7 (5.1)**	**27.6 (4.8)**	**25.9 (4.8)**	**0.001**

Scores less than 4.28 for desire, less than 5.0 for arousal, less than 5.4 for lubrication, less than 5.0 for orgasm, less than 5.0 for satisfaction and less than 5.5 for pain are considered as FSD per individual type.

The FSD scores were significantly lower among those who were on hormonal contraceptives compared with those on non-hormonal IUCD in all the four types (domains) of FSD (Desire, arousal, lubrication and satisfaction), except in orgasm and pain where they were similar in the two groups.

Table 6: Bivariate analysis of contraception type associated with FSD, using IUCD as baseline variable, among women on hormonal contraceptives and non-hormonal IUCD in the FP clinic at KNH, 2019-2020

Hormonal contraceptives versus non-hormonal IUCD		**Total N= 347**	**No FSD n = 178**	**FSD n = 169**	**Odds ratio**	**P value**
Contraceptive group	Non-hormonal	170 (49.0%)	102 (57.3%)	68 (40.2%)	1	
	Hormonal	177 (51.0%)	76 (42.7%)	101 (59.8%)	1.99 (1.30 to 3.06)	0.001
Contraceptive type	IUCD	170 (49.0%)	102 (57.3%)	68 (40.2%)	1	0.06
	COC	63 (18.2%)	29 (16.3%)	34 (20.1%)	1.76 (0.98 to 3.15)	0.06
	POP	34 (9.8%)	16 (9.0%)	18 (10.7%)	1.68 (0.81 to 3.54)	0.17
	DEPO	24 (6.9%)	7 (3.9%)	17 (10.1%)	3.64 (1.43 to 9.25)	0.007
	Jadelle	26 (7.4%)	13 (7.3%)	13 (7.7%)	1.5 (0.66 to 3.43)	0.34
	Implanon	30 (8.7%)	11 (6.2%)	19 (11.2%)	2.59 (1.16 to 5.79)	0.02

Women who were on hormonal contraceptives were associated with two times increased odds of developing FSD, compared with those who were on non-hormonal IUCD, OR: 1.99 (95% CI:1.30 to 3.06).

The use of DEPO was associated with four times increased odds of developing FSD, compared with using non-hormonal IUCD, OR: 3.64 (95% CI:1.43 to 9.25).

The use of implanon was associated with three times increased odds of developing FSD compared with using non-hormonal IUCD, OR: 2.59 (95% CI:1.16 to 5.79).

Table 7: Bivariate analysis of factors associated with FSD among women on hormonal contraceptives and non-hormonal IUCD in the FP clinic at KNH, 2019-2020

Characteristics		**Total N= 347**	**No FSD N = 178**	**FSD n = 169**	**OR 95%CI**	**P value**
Age	Mean (SD)	32.4 (6.6)	32.4 (6.2)	32.4 (7.0)		0.94
Age	≤30 years	151 (43.5%)	74 (41.6%)	77 (45.5%)	1	
	> 30 years	196 (56.5%)	104 (58.4%)	92 (54.4%)	0.85 (0.55 to 1.30)	0.45
Marital status	Single	39 (11.2%)	14 (7.9%)	25 (14.8%)	1	
	Married	294 (84.7%)	158 (88.8%)	136(80.5%)	0.48 (0.24 to 0.96)	0.04
	Div/widowed/separated	14 (4.0%)	6 (3.4%)	8 (4.7%)	0.74 (0.22 to 2.59)	0.65
Education	Primary	62 (17.9%)	22 (12.4%)	40 (23.7%)	1	
	Secondary	113 (32.6%)	45 (25.2%)	68 (40.2%)	0.83 (0.43 to 1.58)	0.572
	Tertiary	172 (49.6%)	111 (62.4%)	61 (36.1%)	0.30 (0.16 to 0.55)	0.001
Occupation	Professional	78 (22.5%)	50 (28.1%)	28 (16.6%)	1	
	Business	159 (45.8%)	76 (42.7%)	83 (49.1%)	1.95 (1.12 to 3.41)	0.02
	Skilled	62 (17.9%)	29 (15.3%)	33 (19.5%)	2.03 (1.03to 4.01)	0.041
	Learner	48 (13.8%)	23 (12.9%)	25 (14.8%)	1.94 (0.93 to 4.03)	0.075
Religion	Catholic	98 (28.2%)	45 (25.3%)	53 (31.4%)	1	
	Protestant	225 (64.8%)	129 (72.5%)	96 (56.8%)	0.63 (0.39 to1.02)	0.06
	Others	24 (2.9%)	4 (2.2%)	20 (11.8%)	4.25 (1.35 to 13.34)	0.07
FGM	No	338 (97.4%)	178 (100%)	160(94.7%)	1	-
	Yes	9 (2.5%)	0	9 (5.3%)	-	
GBV	No	341 (98.3%)	177 (99.4%)	164(97.0%)	1	
	Yes	6 (1.7%)	1 (0.6%)	5 (3.0%)	5.39 (0.62 to 46.68)	0.96
STIs	No	343 (98.8%)	177 (99.4%)	166(98.2%)	1	
	Yes	4 (1.2%)	1 (0.6%)	3 (1.8%)	3.19 (0.32 to 31.06)	0.29

OR – uadjusted Odds Ratio, CI – Confidence Interval.

The women who had tertiary level of education had 70% reduced likelihood of developing FSD, compared with those who had primary level of education.

The women who owned personal businesses had two times increased odds of developing FSD compared with those who were professional.

Table 8 Multivariate analysis of the factors associated with FSD among women on hormonal contraceptives and non-hormonal IUCD in the FP clinic at KNH, 2019-2020

Factors associated with FSD		**AOR (95% CI)**	**P value**
Contraceptive use	Non- Hormonal	1	
	Hormonal	1.71 (1.05 to 2.80)	0.03
Age	Mean	1.01 (0.97 to 1.05)	0.63
Age	≤30	1	
	>30	0.97 (0.59 to 1.58)	0.895
Marital status	Single	1	
	Married	0.56 (0.26 to 1.21)	0.15
	Div/widowed/ Separated	1.15 (0.29 to 4.50)	0.84
Education	Primary	1	
	Secondary	0.72 (0.36to 1.45)	0.35
	Tertiary	0.27 (0.13 to 0.57)	0.001
Religion	Catholic	1	
	Protestant	0.67 (0.40 to 1.12)	0.126
	Others	4.49 (1.36 to 14.87)	0.014
Occupation	Professional	1	
	Business	1.26 (0.65 to 2.48)	0.64
	Technical and Skilled	1.21 (0.55 to 2.25)	0.65
	Unskilled and learner	0.97 (0.41 to 2.25)	0.48

AOR – Adjusted Odds Ratio, CI – Confidence Interval.

The use of hormonal contraceptives were associated with two times increased odds of developing FSD compared with using non-hormonal IUCD, after adjusting for age, marital status, education, religion and occupation.

Having tertiary level of education had 73% reduced likelihood of developing FSD compared with those with primary level of education.

CHAPTER FIVE: DISCUSSION

This cross-sectional comparative study has shown that there was a high prevalence of Female Sexual Dysfunction among women on hormonal contraceptives compared with those on non-hormonal IUCD, in the family planning clinic, at Kenyatta National Hospital. Moreover, after adjusting for age, marital status, occupation and education, being on hormonal contraceptives was associated with two times increased odds of developing FSD, compared with being on non-hormonal IUCD. This high prevalence could be attributed probably to the following: Hormonal balance is necessary for optimal sexual functioning (51). When there is a reduction in estrogen levels, there will be decreased blood supply to the vagina, leading to reduced lubrication, and painful intercourse or dyspareunia. (50, 52, 53, 54). Moreover, sex hormone-binding globulins (SHBG), is a carrier glycoprotein for testosterone and estrogen. Estrogen increases levels of SHBG (7, 10, 55, 56, 57). Progestin may increase or decrease the effect of estrogen on secretion of SHBG. Testosterone has a high binding capacity for SHBG. Thus, estrogen increases SBHG levels in serum. The SBHG binds the free testosterone, reducing its levels. Reduced levels of free testosterone may lead to reduced libido, hence FSD (55, 56, 57, 58, 59, 60). Consequently, hormonal contraceptives have been associated with decreased sexual desire, lubrication, orgasm, satisfaction and increased incidence of dyspareunia (15, 16, 55, 56, 57, 58, 59, 60, 61, 62, 63). This study is comparable to other previous studies.

The prevalence of FSD was significantly higher among those on hormonal contraceptives (57.1%) compared with those on non-hormonal IUCD (40.0%). The FSD prevalence of 57.1% among hormonal contraceptive users, in this study, is comparable to the finding in the Egyptian study by Rabab S. Hassan, et al. (2015) where a prevalence of 54.0% was reported. In the Egyptian study, as the duration of

the use of the hormonal contraceptives increased, the FSD also increased, as follows: The female who used hormonal contraceptive for 6 months up to one year had an FSD prevalence of 54%, the women who used for one year had a prevalence of 71%, those who used for three years had a prevalence of 74% and those who used for more than three years had a prevalence of 78 (42). This study is similar to the Egyptian study in terms of methodology where the FSFI score was used. However, the difference was in terms of stratification based on duration of use. Moreover, the present study mainly consisted of the black Kenyan women of reproductive age, unlike the Egyptian study that had mainly Arabian women.

The FSD prevalence of 40.0% among non-hormonal IUCD users in this present study is also comparable to the Taiwan study by Sakinci M et al (2016) that had a prevalence of FSD of 41% among the non-hormonal Cu-IUCD users (36). Both of these two studies used similar methodology.

The FSD scores of the four different types (domains) of FSD (desire, arousal, lubrication and satisfaction) were significantly lower among the women who were on hormonal contraceptives compared with the non-hormonal IUCD counterparts, except in the cases of orgasm and painful domains where the FSD scores were statistically similar in the two groups. Several studies have previously shown that hormonal contraceptives are associated with decreased sexual desire, lubrication, orgasm, satisfaction and increased incidence of dyspareunia (15, 16, 55, 56, 57, 58, 59, 60, 61, 62, 63).

In this study, age, marital status, religion and occupation were not associated with FSD. The findings in this present study were also comparable to the previous Nigerian study by Nwaga U I. et al (2014) that also found no association between FSD and marital status, religion or occupation. In this study, age was not associated with

developing FSD. This could probably be because the two groups were matched for age (±5 years).). Similar to this present study, Karbasi et al (2006) found no significant relationship between sexual function disorders and age (84). However, several studies have shown that age is associated with FSD, with young age being protective while old age being associated with FSD. According to the study by Hisasue et al (2005), the incidence of sexual function disorders in women rose with aging (81). Also in the study conducted by Berman et al (2003), it was observed that FSD was positively associated with age (82). A Previous study by Ponholzer et al (2005) also showed that all the sexual function disorders in women rose as they aged (83

Having tertiary level of education reduced the likelihood of developing FSD by about 73%, after adjusting for age, marital status, occupation and contraceptive use, AOR: 0.27 (95%CI:0.13 to 0.57). Some studies have shown that the higher the level of education one attains, the less likely she is to have FSD, probably because of highly likelihood of being well informed on sexual education, leading to good health seeking behaviour. This study was comparable to a Nigerian study by Nwaga U I. et al (2014) that also found no statistically significant association between FSD and educational qualification (40).

Having had FGM, GBV or STI had no association with FSD. The presence of previous history of FGM, GBV or STI have been shown to be associated with FSD in the previous studies. In this present study, almost all the women who had FGM, GBV, and STI also had FSD. However, because of the small number of women with these cases (FGM, GBV, STIs) in the FP clinic at KNH, 2019 to 2020, no association of FGM, GBV or STI with FSD was demonstrated. According to a study by Biglu, M.H. et al (2016), FGM is associated with FSD (85). Likewise, in an Egyptian study by

Afefy, Nagwa (2015), FSD was found to be associated with FGM (86). Jamali, S. et al (2016), in an Iranian study, also found that GBV was associated with FSD (87). A previous study by Sedeghi N. et al. (2010), also showed that having a history of STI is associated with FSD (88).

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

This study shows that women on hormonal contraceptives have a higher prevalence of FSD, as measured by FSFI full scale score, compared with their counterparts on non-hormonal IUCD, in the family planning clinic, at Kenyatta National Hospital. After adjusting for age, marital status, education and occupation, women on hormonal contraceptives had two times increased odds of developing FSD, compared with their counterparts on non-hormonal IUCD; and in terms of different types of hormonal contraceptives associated with FSD, DEPO and implanon were strongly associated with FSD. Women on hormonal contraceptives were more likely to suffer from the four types of FSD (desire, arousal, lubrication and satisfaction) compared with their counterparts on non-hormonal IUCD, except for orgasm and pain where the proportions were the same.

6.2 RECOMMENDATION

1. Routine individualized screening of FSD in women during hormonal contraceptive use, based on FSFI questionnaire protocol.
2. A possible association with FSD to be included in the side effect profile of implanon and DMPA information given in the family planning clinic.
3. A case control follow up study to be done to assess whether the use of hormonal contraceptives causes FSD.

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APPENDICES

APPENDIX I: INFORMED CONSENT EXPLANATION FORM

Dear participant, my name is Dr. Julia Dorris Woka Okaka, a postgraduate student in the department of Obstetrics and Gynecology, University of Nairobi.

(The consent explanation form to be read and questions answered in a language in which the patient is fluent).

Your permission is being requested to participate in a study as noted below to be conducted at the family planning clinics at Kenyatta National Hospital. You should understand the following general principles which apply to all in medical research whether normal or patient volunteers:

i. Your agreement to enroll is entirely voluntary
ii. You may withdraw from the study at any time.
iii. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.
iv. After you have read or been taken through the explanation, please feel free to ask any question (s) that will allow you to understand clearly the nature of the study and only participate when you are ready.

The study details include:

Title: The prevalence of Female Sexual Dysfunction among women on hormonal contraceptives attending family planning clinic at Kenyatta National Hospital.

Introduction: Use of hormonal contraceptives may bring about sexual dysfunction as one of their complications, whose psychological effects on the affected person could lead to impaired quality of life in terms of dissatisfaction with the partner, anxiety and low self-esteem in life as a result of impaired sexual function/performance. The study, therefore, intends to establish the prevalence of sexual dysfunction in our set up, thus

bring to attention the need to be aware of its presence when dealing with premenopausal women of reproductive age for their better management.

Objectives of the study: To establish the prevalence (proportion) and types of Female Sexual Dysfunction among women on hormonal contraceptives and non-hormonal Cu-IUCD attending the family planning clinic at Kenyatta National Hospital.

The clinic attendance register and patients' medical cards will assist to sample the patients, and on any of the given study day, any of the patients sampled will become the study participants. You will be asked to go through the consent explanation document. You will be allowed time to ask the researcher or her assistants any question that you may have. When you have understood and are willing to participate, you will be asked to sign the participant's informed written consent form attached to this explanation document. Signing the informed consent form indicates that you have agreed to participate in the study, after which you will be required to fill out the questionnaires that will each take about 15 minutes to complete. No name will appear on the questionnaires. I will request for information from you concerning your health status. This will be in form of questionnaires. You have the right of asking questions where you do not understand.

Benefit: It is hoped that the outcome of the study will lead to awareness of the prevalence and types of Female Sexual Dysfunction in regard to use of contraceptives hence lead to greater understanding on how to manage the conditions. If you are found to have a sexual dysfunction you will be managed accordingly.

Risks: There are no anticipated risks in participating in this study. However, if there are any problems that may arise due to your participation, you will be assisted accordingly.

Confidentiality: Records will be kept confidential and your name will not he used in any resulting publications. Once filled the documents will be kept in a locker only accessible to the researcher.

Contact: If you have any questions regarding the study or participation in this study, you can call the principal researcher: Dr. Julia Woka Okaka on Telephone No. 0729373805.

For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke. The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

APPENDIX II: PARTICIPANT'S INFORMED CONSENT FORM I

The undersigned do hereby volunteer to participate in the study whose nature and purpose has been explained to me fully. I do understand that all the information gathered will be used for purposes of the study only and will be handled in total confidence. I have been given the opportunity to ask questions regarding the study and I have understood. I understand I can withdraw from the study and that I will not lose any benefits or my rights that I may have.

Participant's Number _____Signature _____

Date_____

Researcher's Name _____

Signature _____

Date _____

APPENDIX III: SOCIO DEMOGRAPHIC DATA QUESTIONNAIRE

Study Number _____ Date: _____

Gender_____ Clinic: _____

Age _____ Date of birth_____

1. Marital status. (i) Single (ii) Married (iii) Separated (iv) Divorced (v) Widowed (iv) Cohabiting
2. Highest level of education (i) Nil (ii) Primary (iii) Secondary (iv) College (v) University
3. Occupation. (i) Professional (ii) Business - Personnel (iii) Technical Personnel (iv) Skilled personnel (v) Unskilled Personnel (vi) Learner
4. Religion: (i) Catholic (ii) Protestant (iii) Hindu (iv) Muslim (v) African Traditional (vi) others
5. Personal medical history. When did you start using contraceptives?

   Year_____ Age_____

Are you on any treatment?

Yes No

If yes, what treatment are you taking _____

_____

Have you ever had any medical condition that affected your sexual function?

Yes No

If yes, what was the medical condition _____

How did this medical condition affect your sexual function?

_____

_____

Have you ever experienced any of the following?

Female Gender Mutilation Yes No

Gender Based Violence Yes No

If yes, describe the nature of Gender Based Violence _____

_____

Sexually Transmitted Infection Yes No

Have you ever experienced any form of sexual problems?

Yes No

If yes, describe the nature of sexual problem_____

_____

7. When did you first experience the sexual problems? _____

8. Have you had any form of treatment for sexual problem?

Yes No

If yes, what kind of treatment did you get?

_____

_____

9. Have you ever experienced any problem or your life been affected in any way because of the sexual problem?

Yes No

If yes, what kind of problems or in which way has your life been affected?

_____

_____

_____

10. For how long have you had these problems or your life been affected?

_____

_____

Appendix IV: Appendix A -Female Sexual Function Index (FSFI)

Background and Validation

The Female Sexual Function Index (FSFI), a 19-item questionnaire, has been developed as a brief, multidimensional self-report instrument for assessing the key dimensions of sexual function in women (28) It was developed on a female sample of normal controls and age-matched subjects who met DSM-IV®-TR criteria for female sexual arousal disorder (FSAD) and provides scores on six domains of sexual function (desire, arousal, lubrication, orgasm, satisfaction, and pain) as well as a total score (83).

The FSFI has been validated on clinically diagnosed samples of women with female sexual arousal disorder (FSAD), female orgasmic disorder (FOD), and hypoactive sexual desire disorder (HSDD) (83).

Female Sexual Function Index (FSFI)

Participant's number: Date:

INSTRUCTIONS: These questions ask about your sexual feelings and responses during the past 4 weeks. Please answer the following questions as honestly and clearly as possible.

Your responses will be kept completely confidential.

In answering these questions the following definitions apply:

Sexual activity can include caressing, foreplay, masturbation, and vaginal intercourse.

Sexual intercourse is defined as penile penetration (entry) of the vagina.

Sexual stimulation includes situations like foreplay with a partner, self-stimulation (masturbation), or sexual fantasy.

CHECK ONLY ONE BOX PER QUESTION.

Sexual desire or interest is a feeling that includes wanting to have a sexual experience, feeling receptive to a partner's sexual initiation, and thinking or fantasizing about having sex.

1. Over the past 4 weeks, how often did you feel sexual desire or interest?

☐ 5 = Almost always or always

☐ 4 = Most times (more than half the time)

☐ 3 = Sometimes (about half the time)

☐ 2 = A few times (less than half the time)

☐ 1 = Almost never or never

2. Over the past 4 weeks, how would you rate your level (degree) of sexual desire or interest?

☐ 5 = Very high

☐ 4 = High

☐ 3 = Moderate

☐ 2 = Low

☐ 1 = Very low or none at all

Sexual arousal is a feeling that includes both physical and mental aspects of sexual excitement.

It may include feelings of warmth or tingling in the genitals, lubrication (wetness), or muscle contractions.

3. Over the past 4 weeks, how often did you feel sexually aroused ("turned on") during sexual activity or intercourse?

☐ 0 = No sexual activity

☐ 5 = Almost always or always

☐ 4 = Most times (more than half the time)

☐ 3 = Sometimes (about half the time)

☐ 2 = A few times (less than half the time)

☐ 1 = Almost never or never

4. Over the past 4 weeks, how would you rate your level of sexual arousal ("turn on") during sexual activity or intercourse?

☐ 0 = No sexual activity

☐ 5 = Very high

☐ 4 = High

☐ 3 = Moderate

☐ 2 = Low

☐ 1 = Very low or none at all

5. Over the past 4 weeks, how confident were you about becoming sexually aroused during sexual activity or intercourse?

☐ 0 = No sexual activity

☐ 5 = Very high confidence

☐ 4 = High confidence

☐ 3 = Moderate confidence

☐ 2 = Low confidence

☐ 1 = Very low or no confidence

6. Over the past 4 weeks, how often have you been satisfied with your arousal (excitement) during sexual activity or intercourse?

☐ 0 = No sexual activity

☐ 5 = Almost always or always

☐ 4 = Most times (more than half the time)

☐ 3 = Sometimes (about half the time)

☐ 2 = A few times (less than half the time)

☐ 1 = Almost never or never

7. Over the past 4 weeks, how often did you become lubricated ("wet") during sexual activity or intercourse?

☐ 0 = No sexual activity

☐ 5 = Almost always or always

☐ 4 = Most times (more than half the time)

☐ 3 = Sometimes (about half the time)

☐ 2 = A few times (less than half the time)

☐ 1 = Almost never or never

8. Over the past 4 weeks, how difficult was it to become lubricated (“wet”) during sexual activity or intercourse?

☐ 0 = No sexual activity

☐ 1 = Extremely difficult or impossible

☐ 2 = Very difficult

☐ 3 = Difficult

☐ 4 = Slightly difficult

☐ 5 = Not difficult

9. Over the past 4 weeks, how often did you maintain your lubrication (“wetness”) until completion of sexual activity or intercourse?

☐ 0 = No sexual activity

☐ 5 = Almost always or always

☐ 4 = Most times (more than half the time)

☐ 3 = Sometimes (about half the time)

☐ 2 = A few times (less than half the time)

☐ 1 = Almost never or never

10. Over the past 4 weeks, how difficult was it to maintain your lubrication ("wetness") until completion of sexual activity or intercourse?

☐ 0 = No sexual activity

☐ 1 = Extremely difficult or impossible

☐ 2 = Very difficult

☐ 3 = Difficult

☐ 4 = Slightly difficult

☐ 5 = Not difficult

11. Over the past 4 weeks, when you had sexual stimulation or intercourse, how often did you reach orgasm (climax)?

☐ 0 = No sexual activity

☐ 5 = Almost always or always

☐ 4 = Most times (more than half the time)

☐ 3 = Sometimes (about half the time)

☐ 2 = A few times (less than half the time)

☐ 1 = Almost never or never

12. Over the past 4 weeks, when you had sexual stimulation or intercourse, how difficult was it for you to reach orgasm (climax)?

☐ 0 = No sexual activity

☐ 1 = Extremely difficult or impossible

☐ 2 = Very difficult

☐ 3 = Difficult

☐ 4 = Slightly difficult

☐ 5 = Not difficult

13. Over the past 4 weeks, how satisfied were you with your ability to reach orgasm (climax) during sexual activity or intercourse?

☐ 0 = No sexual activity

☐ 5 = Very satisfied

☐ 4 = Moderately satisfied

☐ 3 = About equally satisfied and dissatisfied

☐ 2 = Moderately dissatisfied

☐ 1 = Very dissatisfied

14. Over the past 4 weeks, how satisfied have you been with the amount of emotional closeness during sexual activity between you and your partner?

☐ 0 = No sexual activity

☐ 5 = Very satisfied

☐ 4 = Moderately satisfied

☐ 3 = About equally satisfied and dissatisfied

☐ 2 = Moderately dissatisfied

☐ 1 = Very dissatisfied

15. Over the past 4 weeks, how satisfied have you been with your sexual relationship with your partner?

☐ 5 = Very satisfied

☐ 4 = Moderately satisfied

☐ 3 = About equally satisfied and dissatisfied

☐ 2 = Moderately dissatisfied

☐ 1 = Very dissatisfied

16. Over the past 4 weeks, how satisfied have you been with your overall sexual life?

☐ 5 = Very satisfied

☐ 4 = Moderately satisfied

☐ 3 = About equally satisfied and dissatisfied

☐ 2 = Moderately dissatisfied

☐ 1 = Very dissatisfied

17. Over the past 4 weeks, how often did you experience discomfort or pain during vaginal penetration?

☐ 0 = Did not attempt intercourse

☐ 1 = Almost always or always

☐ 2 = Most times (more than half the time)

☐ 3 = Sometimes (about half the time)

☐ 4 = A few times (less than half the time)

☐ 5 = Almost never or never

18. Over the past 4 weeks, how often did you experience discomfort or pain following vaginal penetration?

☐ 0 = Did not attempt intercourse

☐ 1 = Almost always or always

☐ 2 = Most times (more than half the time)

☐ 3 = Sometimes (about half the time)

☐ 4 = A few times (less than half the time)

☐ 5 = Almost never or never

19. Over the past 4 weeks, how would you rate your level (degree) of discomfort or pain during or following vaginal penetration?

☐ 0 = Did not attempt intercourse

☐ 1 = Very high

☐ 2 = High

☐ 3 = Moderate

☐ 4 = Low

☐ 5 = Very low or none at all

Thank you for completing this questionnaire.

Appendix IV B: FSFI Domain Scores and Full Scale Score

The individual domain scores and full scale (overall) score of the FSFI can be derived from the computational formula outlined in the table below. For the individual domain scores, add the scores of the individual items that comprise the domain and multiply the sum by the domain factor (see below). Add the six domain scores to obtain the full scale score. It should be noted that within the individual domains, a domain score of zero indicates that the subject reported having no sexual activity during the past month. Subject scores can be entered in the right-hand column.

Table 9: Female Sexual Function Index Score

DOMAIN	QUESTIONS	SCORE RANGE	FACTOR	MINIMUM SCORE	MAXIMUM SCORE	SCORE
DESIRE	1,2	1- 5	0.6	1.2	6.0	
AROUSAL	3, 4, 5, 6	0 – 5	0.3	0	6.0	
LUBRICATION	7, 8, 9, 10	0 – 5	0.3	0	6.0	
ORGASM	11, 12, 13	0 – 5	0.4	0	6.0	
SATISFACTION	14, 15, 16	0 (or 1 -) 5	0.4	0	6.0	
PAIN	17, 18, 19	1 – 5	0.4	0	6.0	
FULL SCALE SCORE RANGE				12.0	36.0	

A score ≤ 26.55 is classified as FSD.* A score closer to ≤ 26.55 is described as being at risk of FSD.

Scores less than 4.28 for desire, less than 5.0 for arousal, less than 5.4 for lubrication, less than 5.0 for orgasm, less than 5.0 for satisfaction and less than 5.5 for pain are considered as FSD per individual type.

From Rosen R, et al. (2000)-The Female Sexual Function Index (FSFI): A Multidimensional Self-Report Instrument for the Assessment of Female Sexual Function. Journal of Sex and Marital Therapy. 2000;26(2):191-208. (89, 90).

APPENDIX V: CONSENT FORM- KISWAHILI

FEMALE SEXUAL DYSFUNCTION AMONG WOMEN OF REPRODUCTIVE AGE ON HORMONAL CONTRACEPTIVES COMPARED WITH THOSE ON NON-HORMONAL CONTRACEPTION, 2019-2020

UNIVERSITY OF NAIROBI/KENYATTA NATIONAL HOSPITAL

ETHICS AND RESEARCH COMMITTEE (ERC)

FOMU YA KIBALI CHA KUSHIRIKI KWENYE UTAFITI

Jina la mtafiti mkuu: Julia Dorris Woka Okaka, mwanafunzi wa uzamili katika idara ya ugonjwa ya akina mama na wanawake, chuo kikuu cha Nairobi.

Jina la mtu wakuwasilisha kuhusu utafiti: Dr. Julia Woka Dorris Okaka 072933805

Taarifa kutoka kwa utafiti

Unaombwa kushiriki katika utafiti huu. Dhumuni ya hii fomu ya idhini ni kukupa habari Zaidi kuhusu utafiti huu ili iweze kukusaidia kuamua kama ungependa kushiriki katika utafiti huu au hapana. Tunaomba uisome hii fomu kwa makini. Watafiti wataongea na wewe kuhusu utafiti huu na uko huru kuuliza maswali wakati wowote kuhusiana na chochote tutakachokifanya katika utafiti huu, hatari na manufaa ya kushiriki katika utafiti huu na pia haki zako kama mshiriki wa utafiti huu. Tukishakujibu maswali yako yote, utachagua kushiriki kwenye huu utafiti au kukataa. Kama utakubali kushiriki katika utafiti huu, utaombwa kuweka sahihi katika hii fomu ya idhini. Utapewa nyaraka kuweka kwa ukumbusho wako.

LENGO LA UTAFITI

Madhumuni ya utafiti huu ni kuelewa wingi wa matatizo ya kufanya ngono kati ya wanawake wanaotumia njia ya upangaji uzazi wa homoni kulinganisha na wale wanaotumia njia ya upangaji uzazi usiona homoni (Cu-IUCD), katika kliniki ya upangaji uzazi, hospitali ya kitaifa ya Kenyatta.

UTARATIBU WA UTAFITI

Baada ya kusoma, kukubali na kuweka sahihi kwa fomu ya idhini utaulizwa maswali kuhakikisha kuwa unayo mahitaji yote ya kushiriki katika utafiti huu. Ukikubali kushiriki, itakuchukua muda wa robo saa kukamilisha utafiti huu. Ikiwa hautaweza kukamilisha utafiti huu leo, tutaomba urudi katika muda wa mwezi moja ukiwa tayari kushiriki.

Ukiamua kutoshiriki kwenye utafiti huu, ama kama hautatimiza matakwa yote ya utafiti huu, huenda tukatumia majibu yako kama vile miaka na jinsia yako.

ARI ZINAZOAMBATANA NA KUSHIRIKI KATIKA UTAFITI

Pia maswali utakayo ulizwa leo yanaweza kuwa maswali nyeti kwako. Mazungumzo au taarifa yeyote tutakayopata toka kwako itatunzwa kwa siri kubwa na kutoka jibu ni hiari yako. Kama utakataa kushiriki kwa huu utafiti, bado utaendele kupokea matibabu unayohitaji, na haita adhiri uhusiano wako na cliniki hii. Hautalipishwa ada kushiriki katika utafiti huu. Kama unatatizo lolote linalohusiana na utafiti unaweka kuwasiliana na Dk. Julia Dorris Woka Okaka **0729373805** aweze kukusaidia.

MANUFAA YA KUSHIRIKI KATIKA UTAFITI

Kuna manufaa kwako unaposhiriki katika utafiti huu. Utajifunza Zaidi kuhusu matatizo ya kufanya ngono yanayohusiana na kutumia upangaji uzazi. Hii itasaidia wauguzi wako kujua jinsi gani wakusaidia ikijulikana una matatizo hayo.

WADHAMINI WA UTAFITI HUU

Jina: Dkt. Julia Dorris Woka Okaka

USIRI WA TAARIFA ZA UTAFITI

Matokeo ya utafiti huu itapewa daktari wako na mashirika yanayoshirikiana katika utafiti huu. Walakini, haitawezekana kukutambua wewe kibinafsi kutoka kwa hii habari. Kikundi cha utafiti kitakupatia namba ya utambulisho. Na yautamubulisho (code) sio jina lako ama habari yoyote ambayo inaweza tumika kukutambulisha itatumika. Rekodi za utafiti ndiyo pekee yao watakuwa na funguo. Kuchapishwa kokote matokeo ya huu utafiti hautatumia jina lako kukutambulisha wewe binafsi.

Rekodi zako zinaweza pitiwa na Ethics and Research Committee of University of Nairobi.

Tafadhali kumbuka ya kwamba ni chaguo lako kushiriki ama kutoshiriki katika huu utafiti wa kufuatilia. Una kuacha kushiriki katika huu utafiti wakati wowote. Bado utaendelea kupata matibabu yako ya kiafya kikamilifu kama hautashiriki katika huu utafiti.

MALIPO

Hautalipwa ridhaa kwa muda wako uliotumia katika kumaliza uchunguzi unaohusiana na huu utafiti.

MAJERUHI YATOKANAYO NA UTAFITI HUU

Kama umejeruhiwa kwa sababu ulishiriki katika utafiti, mpigie Dkt. Julia Dorris Woka Okaka **0729373805** haraka iwezekanavyo ili aweze kukupatia matibabu au kukutafutia njia ya kupata matibabu.

Nambari ya mwenye kukuchukua kibali cha kushiriki utafiti: _____

Tarehe: _____

Kwa kusingatia yote hapa juu, ninakubali kushiriki katika huu utafiti. Nimesoma hii fom,u ya kukubali (ama imesomwa na nikaelezewa wazi), maswali yangu yote yamejibika na ninakubali kushiriki katika huu utafiti. Na ninakubali kupokea nakala ya fomu ya kukubali. Kama nina maswali Zaidi kuhusu utafiti ama majelaha yanayohusiana na utafiti, nitawasiliana na mtafiti Daktari Julia Dorris Woka Okaka kwa namba ya simu: 0729373805. Na maswali kuhusu haki zangu kama mshiriki katika utafiti ama malalamiko kuhusu utafiti, wasiliana na msimamizi wa ERC kwa namba ya simu:

SAHIHI AMA ALAMA YA MSHIRIKI: _____

Tarehe: _____

(Lazima tarehe iwekwe na mshiriki kama amesoma)

SAHIHI YA MSHAHIDI: _____ Tarehe: _____

(Kama hana elimu ya kumwezesha kusoma lazima tarehe iandikwe na mshahidi)

APPENDIX VI: SOCIO DEMOGRAPHIC DATA QUESTIONNAIRE

Nambari ya Utafiti _____

Tarehe: _____ Jinsia: _____

Kliniki: _____

Tarehe ya Kuzaliwa: _____

6. Hali ya ndoa (i) Sijaolewa (ii) Nimeolewa (iii) tumeachana (iv) talaka (v) mjane (iv) kuishi bila kuona rasmi (Cohabiting)

7. Elimu ya juu (i) Hakuna (ii) Msingi (iii) Sekondari (iv) Chuo (v) Chuo Kikuu

8. Kazi (i) Mtaalamu (ii) Biashara – kibinafsi (iii) Kiufundi (iv) mfanyi kazi wenye ujuzi (v) Mfanyikazi usionaujuzi (vi) Mwanafunzi

9. Dini (i) Katoliki (ii) Kiprotestanti (iii) Kihindu (iv) Mwislamu (v) Dini ya asili ya Kiafrika T (vi) Mengine

10. Historia ya matibabu. Ni lini ulianza kutumia njia ya upangaji uzazi ?

Mwaka_____ Umri_____

Uko kwa matibabu yoyote?

Ndio La

Kama ndio, unatumia matibabu gani? _____

_____

Ushawahi kukabiliwa na mojawapo ya yafuatayo?

Ukeketaji ya wanawake? Ndio La

Dhuluma ya Kimapenzi? Ndio La

Kama ndio, elezea zaidi kuhusu dhuluma ya kimapenzi hio

_____

_____

Ugonjwa wa zinaa? Ndio La

Ushawahi kupatikana na shida ngono? Ndio La

Kama ndio, elezea aina ya shida ya ngono hio _____

_____

7. Ni lini ulipatikana na shida ya hiyo ngono?

_____

8. Ushawahi kupata matibabu ya shia ya ngono? Ndio La

Kama ndio, elezea aina ya matibabu uliyopata

_____

_____

9. Ushawahi kupata shida kutokana na hiyo shida ya ngono? Ndio La

Kama ndio, ni shida aina gani ama ni vipi maisha yako yameathirika?

_____

_____

11. Ni kwa muda gani umepata shida hii ya ngono ama maisha yako kuathirika?

_____

_____

Appendix VII -Female Sexual Function Index (FSFI)

Background and Validation

Kielezo cha ngono kwa mwanamke-The Female Sexual Function Index (FSFI), ni orodha ya maswali 19 kuhusu kufanya ngono kwa wanawake. Inasehemu sita ya mkusanyiko ya maswali (hamu/desire, msisimuko/arousal, kumwaga mafuta/lubrication, kilele/orgasm, kuridhika/satisfaction, na uchungu/pain)

The FSFI ni dodoso, ama orodha ya maswali 19 kuhusu kufanya ngono kwa wanawake, ya kutambua wanawake walionamatatizo ya kushiriki ngono.

Female Sexual Function Index (FSFI)

Nambari ya Utafiti: Tarehe:

MAELEKEZO: Maswali haya yanauliza kuhusu unavyohisi na kushiriki ngono kwa muda wa wiki nne zilizopita. Tafadhali jibu maswali yafuatayo kwa uaminifu na uwazi uwezekanavyo.

Majibu yako yatawekwa siri.

Kwa kujibu maswali haya, fafanuzi zifuatazo zitatumika:

Kushiriki ngono ni pamoja na kupapasa, punyeto na kufanya ngono.

Kufanya ngono imefafanuliwa kama kuingiza uume kwa uke.

Kusisimua ngono ni pamoja na kupapasa, fikra za ngono na panyeto (maturbation).

CHECK ONLY ONE BOX PER QUESTION.

Hamu ya ngono ni pamoja na kuhisi kushiriki ngono, kufikiria kuhusu ngono ama kuhisi kupokea mpenziyo.

1. Kwa muda wa wiki 4 uliyopita, ni mara ngapi ulihisi ama kufikiria kuhusu ngono?

☐ 5 = Wakati wote

☐ 4 = Wakati mwingi (Zaidi ya nusu ya muda huo)

☐ 3 = Wakati mwingine (karibu nusu ya muda huo)

☐ 2 = Wakati mfupi (chini ya nusu ya muda huo)

☐ 1 = Kamwe ama hapana

2. Kwa muda wa wiki 4 uliopita, ungepima kiwango chako cha hamu ya kushiriki ngono vipi?

☐ 5 = Juu zaidi

☐ 4 = Juu

☐ 3 = Wastani

☐ 2 = Chini

☐ 1 = Chini Zaidi ama hakuna kabisa

Msisimko wa ngono ni hisia inayojumuisha msisimko wa mwili na fikra.

3. Kwa muda wa wiki 4 uliopita, ni mara ngapi ulihisi msisimko wa ngono wakati ulipofanya/shiriki ngono?

☐ 0 = Sikushiriki ngono

☐ 5 = Muda wote

☐ 4 = Wakati mwingi (Zaidi ya nusu ya wakati wa kufanya ngono)

☐ 3 = Wakati mwingine (karibu nusu ya wakati wa kufanya ngono)

☐ 2 = Wakati mchache (chini ya nusu ya wakati wa kufanya ngono)

☐ 1 = Hapana

4. Kwa muda wa wiki 4 uliopita, unaweza kupima vipi kiwango cha msisimko wa ngono wakati wa kufanya ngono?

☐ 0 = Sikushiriki ngono

☐ 5 = Juu zaidi

☐ 4 = Juu

☐ 3 = Wastani

☐ 2 = chini

☐ 1 = Chini Zaidi ama hakuna kabisa

5. Kwa muda wa wiki 4 uliopita, Nikiwango gani cha kujiamini ulichokuwanacho kuwa ungepata kusisimka (sexually aroused) wakati wakushiriki ngono?.

☐ 0 = Sikushiriki ngono

☐ 5 = Kiwango cha juu Zaidi cha kujiamini

☐ 4 = Kiwango cha juu cha kujiamini

☐ 3 = Kiwango cha wastani cha kujiamini

☐ 2 = kiwango cha chini cha kujiamini

☐ 1 = kiwango cha chini Zaidi cha kujiamini

1. Kwa muda wa wiki 4 uliopita, ni mara ngapi umeridhika na msisimko wako wakati wa kushiriki ngono?

☐ 0 = Sikushiriki ngono

☐ 5 = Karibu kila wakati ama kila wakati

☐ 4 = Wakati mwingi (Zaidi ya nusu ya wakati wa kushiriki ngono)

☐ 3 = Wakati mwingine (karibu nusu ya wakati wote wa kushiriki ngono)

☐ 2 = Wakati mchache (chini ya nusu ya wakati wote wa kushiriki ngono)

☐ 1 = Kamwe

2. Kwa muda wa wiki 4 uliopita, ni mara ngapi ulimwaga/lowa ufuta (sexually get lubricated) ukishiriki ngono?

☐ 0 = Sikushiriki ngono

☐ 5 = Karibu kilawakati

☐ 4 = Wakati mwingi (Zaidi ya nusu ya wakati wa kushiriki ngono)

☐ 3 = Wakati mwingine (karibu nusu ya wakati)

☐ 2 = Wakati mchache (chini ya nusu ya wakati)

☐ 1 = Kamwe

3. Kwa muda wa wiki 4 uliopita, ni kiwango ngani cha ugumu ulichopata kumwaga/lowa ufuta wakati wa kushiriki ngono?

☐ 0 = Sikushiriki ngono

☐ 1 = Ilikuwa vingumu zaidi ama sikumwaga/kulowa

☐ 2 = Vigumu zaidi

☐ 3 = Vigumu

☐ 4 = Vigumu kiasi

☐ 5 = Hakukuwa na ugumu wowote

4. Kwa muda wa wiki 4 uliopita, ni mara ngapi uliweza kudumisha umwagikaji/kulowa ufuta wakati wa kushiriki ngono?

☐ 0 = Sikushiriki ngono

☐ 5 = Kila wakati

☐ 4 = Wakati mwingi (zaidi ya nusu ya wakati)

☐ 3 = Wakati mwingine (karibu nusu ya wakati)

☐ 2 = Wakati mchache (chini ya nusu ya wakati)

☐ 1 = Kamwe sikudumisha

5. Kwa muda wa wiki 4 uliopita, ni kiwango kipi cha ugumu ulikuwa kudumisha umwagikaji/kulowa ufuta mpaka kukamilika kwa kushiriki ngono?

☐ 0 = Sikushiriki ngono

☐ 1 = Vigumu zaidi sana ama haikuwezekana

☐ 2 = Vigumu zaidi

☐ 3 = Vigumu

☐ 4 = Vigumu kidogo

☐ 5 = Hakukuwa na ugumu

11. Kwa muda wa wiki 4 uliopita, uliposhiriki ngono, ni mara ngapi uliweza kufikia kilele (orgasm/climax)?

☐ 0 = Sikushiriki ngono

☐ 5 = Karibu kila wakati ama kila wakati

☐ 4 = Wakati mwingi (zaidi ya nusu ya wakati)

☐ 3 = Wakati mwingine (nusu ya wakati)

☐ 2 = Wakati mchache (chini ya nusu ya wakati)

☐ 1 = Kamwe sikufikia kilele

12. Kwa muda wa wiki 4 uliopita, uliposhiriki ngono, kiwango ngani cha ugumu ulikuwa kuufikia kilele (orgasm/climax)?

☐ 0 = Sikushiriki ngono

☐ 1 = Vigumu zaidi sana ama haikuwezekana

☐ 2 = Vigumu zaidi

☐ 3 = Vigumu

☐ 4 = Vigumu kidogo

☐ 5 = Hakukuwa na ugumu

13. Kwa muda wa wiki 4 uliopita, nikiasi gani ya kuridhika na uwezo wako wa kuufikia kilele (orgasm/climax) uliokuwa nayo wakati wa kushiriki ngono?

☐ 0 = Sikushiriki ngono

☐ 5 = Kuridhika sanaVery satisfied

☐ 4 = Kuridhika kiasi

☐ 3 = Karibu kiwango sawa cha kuridhika na kutoridhika

☐ 2 = Kutoridhika kiasi

☐ 1 = Kutoridhika zaidi

14. Kwa muda wa wiki 4 uliopita, kwa kiwango gani uliridhika na hisia ya kukaribiana wakati wa kushiriki ngono na mpenzi wako?

☐ 0 = Sikushiriki ngono

☐ 5 = Kuridhika zaidi

☐ 4 = Kuridhika kiasi

☐ 3 = Kuridhika na kutoridhika kwa kiwango sawa

☐ 2 = Kutoridhika kiasi

☐ 1 = Kutoridhika zaidi

15. Kwa muda wa wiki 4 uliopita, nikiwango ngani uliridhishwa na kushiriki ngono na mpenzi wako?

☐ 5 = Kuridhika zaidi

☐ 4 = Kuridhika kiasi

☐ 3 = Kuridhika na kutoridhika kwa kiwango sawa

☐ 2 = Kutoridhika kiasi

☐ 1 = Kutoridhika zaidi

16. Kwa muda wa wiki 4 uliopita, ni kwa kiwango gani umeridhika na maisha yako ya ngono kwa jumla?

☐ 5 = Kuridhika zaidi

☐ 4 = Kuridhika kiasi

☐ 3 = Kuridhika na kutoridhika kwa kiwango sawa

☐ 2 = Kutoridhika kiasi

☐ 1 = Kutoridhika zaidi

17. Kwa muda wa wiki 4 uliopita, ni mara ngapi ulihisi uchungu wakati wa uke wako ulipopenywa na uume?

☐ 0 = Sikujaribu kufanya ngono

☐ 1 = Karibu wakati wote ama wakati wote

☐ 2 = Wakati mwingi (zaidi ya nusu ya wakati)

☐ 3 = Wakati mwingine (nusu ya wakati)

☐ 4 = Wakati mchache (chini ya nusu ya wakati)

☐ 5 = Kamwe sikuhisi uchungu

18. Kwa muda wa wiki 4 uliopita, ni mara ngapi ulihisi uchungu wakati uke wako ulipenywa na uume?

☐ 0 = Sikushiriki ngono

☐ 1 = Karibu wakati wote ama kilawakati

☐ 2 = Wakati mwingi (zaidi ya nusu ya wakati)

☐ 3 = Wakati mwingine (nusu ya wakati)

☐ 4 = Wakati mchache (chini ya wakati)

☐ 5 = Kamwe sikuhisi uchungu

19. Kwa muda wa wiki 4 uliopita, kiwangokipi cha uchungu ulihisi wakati uke wako ulipopenywa na uume?

☐ 0 = Sikushiriki ngono

☐ 1 = Kiwango cha juu zaidi

☐ 2 = Kiwango cha juu

☐ 3 = Kiwango cha kiasi

☐ 4 = Kiwango chini

☐ 5 = Kiwango cha chini zaidi ama hakukuwa na uchungu kamwe

Asante sana kwa kukamilisha orodha ya maswali ya utafiti huu.

Table 10: Budget

TEST	COST IN KSH	TOTAL
PROPOSAL WRITING		
Typing/Typesetting	5, 000	5,000
Printing and Photocopying	5,000	5,000
DATA COLLECTION		
Assistants	30,000	30,000
Data Entry	20,000	20,000
Data Analysis	40,000	40,000
FINAL THESIS	10,000	10,000
MISCELANEOUS	5000	5000
TOTAL	115, 000	115, 000

Table 11: Research Timeline

The timeline for the research including dissemination of the study results is as follows:

ACTIVITY	**START**	**COMPLETE**
Proposal concept Development	1ST January 2019	25TH April 2019
Proposal Writing	30TH April 2019	31ST JUNE 2019
Departmental presentation of Proposal	1ST JULY	31ST AUGUST 2019
IREC Approval	1ST SEPTEMBER 2019	31ST OCTOBER 2019
Research	1ST DEMBER 2019	30th FEBRUARY 2020
Data Analysis	1ST MARCH 2019	14th MARCH 2020
Thesis Writing	15th MARCH 2020	30th APRIL 2020
Departmental Defense	8th MAY 2020	

KNH-UON ERC APPENDIX 1

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Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/477

23rd December , 2019

KENYATTA NATIONAL HOSPITAL * APPROVED 23 DEC 2019 KNH/UoN-ERC P. O. BOX 20723 - 00202 NAIROBI

Dr. Julia Dorris Woka Okaka
Reg. No.H58/8336/2017
Dept.of Obstetrics and Gynaecology
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Okaka

RESEARCH PROPOSAL: FEMALE SEXUAL DYSFUNCTION AMONG WOMEN ON HORMONAL CONTRACEPTIVES COMPARED WITH THOSE ON NON-HORMONAL INTRAUTERINE CONTRACEPTIVE DEVICE AT THE KENYATTA NATIONAL HOSPITAL (P743/08/2019)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 23rd December 2019 – 22nd December 2020.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g. Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website**http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept. of Obstetrics and Gynaecology, UoN
Supervisors: Dr. Diana Ondieki, Dept.of Obs & Gynae, UoN
Dr. Margaret Kilonzo, Dept.of Obs & Gynae, UoN

FEMALE SEXUAL DYSFUNCTION AMONG WOMEN ON HORMONAL CONTRACEPTIVES COMPARED WITH THOSE ON NON-HORMONAL INTRAUTERINE CONTRACEPTIVE DEVICE AT THE KENYATTA NATIONAL HOSPITAL, 2019-

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