RESEARCH ARTICLE

Continuation and user satisfaction of the levonorgestrel intrauterine system (LNG IUS) contraceptive in Nigeria [version 1; peer review: 1 approved, 1 approved with reservations]

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Abstract

Background: The hormonal intrauterine device or intrauterine system (IUS) also known as the levonorgestrel intrauterine system (LNG-IUS) is a highly effective hormonal intra-uterine contraceptive. However, services offering the method are not widely available in Nigeria and little evidence exists on the dynamics of its use. We examined the continuation rate and satisfaction with the IUS among the user population.

Methods: This prospective longitudinal phone survey involved a baseline survey of users at two-weeks post-insertion of the LNG IUS, recruited from 40 clinics across 17 states in Nigeria, with a follow-up survey at the 3rd and 12th months. A total of 208 users were interviewed at baseline, 98 at three months, and 73 at 12 months. User family planning and the IUS use experiences were elicited, as well as the continuation rate and satisfaction with the method at three and 12 months.

Results: At three- and 12 months post-insertion, 96.9% (95% CI: 91.3, 99.3) and 91.8% (95% CI: 82.9, 96.9), respectively, reported still using the LNG IUS, with none out of the few users who discontinued the method reporting a method failure. Discontinuation was mainly a result of the experience of menstrual bleeding or amenorrhea (25.0%), experiences of pain with the method (18.8%), and partner complaining about strings (16.7%). High satisfaction with the LNG IUS (76.5% at three months and 86.3% at 12 months post-insertion) was reported. Satisfaction with LNG IUS was significantly associated with not having breast tenderness/pain (88.2%) and no vaginal bacterial infection (87.5%) at 12 months compared to experiencing breast tender/pain (50.0%) and vaginal infection (0.0%) ($p<0.05$).

Conclusion: High user continuation and satisfaction with IUS indicates the positive potential of the method as a contraceptive in Nigeria.

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Keywords
Levonorgestrel Intrauterine System (LNG IUS), contraceptive method discontinuation, contraceptive method mix, Nigeria Family Planning.

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Introduction

Discontinuation of contraception among women in Nigeria is one of the main challenges with contraceptive use, together with generally low use of contraception. The recent national demographic health survey report (NDHS 2018) indicates that about 41% of women who had an episode of use of contraception discontinued the contraception within 12 months of use[1]. Contraceptive discontinuation and dissatisfaction with a method occur due to several reasons which may be method related. While the desire to become pregnant is one of the major reasons why a woman will discontinue contraception, method-related reasons such as side effects, method failure, and the need for a more effective method are also prominent reasons for method discontinuation among women who still wish to prevent pregnancy. Discontinuation of contraceptives often leads to unwanted pregnancies and reduces the effort of family planning (FP) programs[2]. Studies show that a sizable proportion of women become exposed to the risk of unintended births after discontinuation of contraceptives[3,4]. In Nigeria, it has been reported that an estimated 15.6% of unintended pregnancies are among women who discontinued contraception in the last seven months[4]. Even higher proportions of unintended births have also been reported in other countries as a result of the discontinuation of contraceptives in the last three months[3]. Serious reproductive consequences of discontinuation because of reported method failure and method-related reasons can occur. Accidental pregnancies that end in miscarriage, stillbirth, or abortion have been reported[3]

In many developing countries including Nigeria, many health outlets providing services for modern contraception are highly constrained on the method mix available for potential users[5]. It is widely known that limited method choice can hinder the uptake and use of contraception, and has been linked with dissatisfaction and discontinuation of contraception[6,7]. The modern contraceptive method mix in Nigeria comprises mainly injectable contraceptives (33.8%), pills (23%), male condoms (18.1%), Implant (10.9%), and intra-uterine devices (IUDs) (5.2%). Other methods such as the lactational amenorrhea method (LAM) make up about 4.8%, while female and male sterilization make up 1.6% and 0.2% of the modern contraceptive method mix, respectively[8]. Global data is available on the dynamics of contraceptive use as it relates to the discontinuation of methods. According to data from 19 different Demographic Health Survey (DHS) participating countries, an average of 38% of women reported discontinuing their use of reversible methods by the 12th month and 64% by the 36th month[3]. The lowest 12-month discontinuation rate was noted for the intrauterine device (IUD; 13%) and the highest was for condoms (50%), while the pill and injectable contraceptives were discontinued by about 40% of users within the first 12 months of use. Contraceptive continuation indicates the acceptability of a contraceptive method, and contraceptive continuation rate is the cumulative probability that acceptors of a contraceptive method will still be using any contraceptive method offered by a program after a specified period[9]. Given this understanding, a high continuation rate of a method indicates users' high level of compliance with the method.

From the pattern of contraceptive method-use according to the Nigeria 2018 National Demographic Health Survey, the national prevalence of 5% of IUD users, use mainly the copper IUD, which is the most common intrauterine contraceptive available in FP clinics in Nigeria. Meanwhile, other types of intrauterine devices such as the hormonal IUD which is a progestin-based intra-uterine delivery system and is a long-acting and reversible contraceptive (LARC), also exist. However, the hormonal IUD does not contribute to the proportion of intrauterine contraceptives used by women[10]. In one study in Zaria Nigeria, of all the 1104 women who opted for an IUD as a method of contraception only 68 (6.1%) women chose the hormonal IUD[11]. This is in contrast to other countries; for example in the US, where the proportion of IUD users has been reported as 12%, with 74% of the users of the intrauterine contraceptives chosing the hormonal IUD[12]. In Nigeria, the use of the hormonal IUD is limited and is widely unavailable to users of contraceptives from both public and private clinics. The limited use of the method is mainly due to its high cost; a unit of the LNG IUS brand Mirena®, which is manufactured by Bayer Healthcare Pharmaceuticals Inc., costs between 25,000 to 90,000 Nigerian Naira, which is currently equivalent to about $69 – $250, compared with the copper IUD, which costs about $5 or less at private clinics and is free of charge in government clinics. In addition, the hormonal IUD method has been relatively recently introduced in the country despite its decades of existence since its development in the 1970s[4,13]. There is also the issue of the availability of providers who are trained to provide the method, thus limiting its use.

The hormonal IUD is a T-shaped device comprising a cylinder containing 52 mg of levonorgestrel, with an average release of 14µg of levonorgestrel every 24 hours of the life of the IUS[14]. The Mirena® LNG IUS that is produced by Bayer Healthcare Pharmaceuticals Inc is indicated to have an effective duration of up to 5 years. However, clinical trials suggest that the LNG IUS can provide contraceptive protection for up to 7 years[15,16]. From a recent study trial, a brand of the IUS Lilelleta developed by Medicine360 (registered under the trade name as Avibela™ in the FP2020 countries including Nigeria), which was previously labeled for use for 3 years has also been indicated to have an effective duration over five years[17]. Eliora another brand of the hormonal IUD developed by Pregna is similar to the Mirena having an effective duration of 5 years[18]. The IUS functions locally in the uterus by thickening the cervical mucus and suppressing endometrial proliferation, thus inhibiting conception. The IUS is known to have both contraceptive and non-contraceptive health benefits in the treatment of menorrhagia, endometriosis, and endometrial hyperplasia[14]. The method is very convenient as it requires nothing else to be done regularly to maintain contraception until after five years when the device can be replaced.

Most side effects of the IUS are transient and include changes in menstrual bleeding pattern, headache, abdominal cramps, breast tenderness, and weight gain[13].

To expand the range of contraceptive options available in the country and to improve the acceptability of contraception, the introduction of new and effective methods such as the hormonal IUS as a strategy to increase contraceptive uptake has been the focus of some FP interventions and organizations that are piloting roll out of new and affordable IUS to potential users in Nigeria. For instance, since 2017 the Society for Family Health (SFH) has been supporting service provision for the LNG IUS as part of a broad range of options available in 40 private health clinics across 17 states in Nigeria, using donations of the registered product in Nigeria from the International Contraceptive Access (ICA) Foundation. To better understand the potential of the hormonal IUS method to contribute to the contraceptive method mix in Nigeria, this study was therefore undertaken to assess and document the continuation of use of the LNG IUS and satisfaction with the method, as well as user characteristics and experiences that may influence continuation and satisfaction among the user population. This will add to the existing body of knowledge on the method and document the experiences of users of the method in Nigeria. If users show high satisfaction and continuation with the IUS, these findings will go a long way to encourage adoption and utilization of the method by users and provide the motivation for its recommendation by FP providers and clinicians, both as a contraceptive and for its non-contraceptive benefits such as treatment of menorrhagia and other gynecological disorders.

Methods

Ethical statement

The study protocol was reviewed by the National Health Research Ethics committee in 2017 and ethical approval was obtained (NHREC/01/01/2007-05/02/2017). Given that data collection in this study was done via phone interviews, oral informed consent was deemed adequate and was obtained from all participants. The consent to partake in the study was recorded by the researchers along with responses of respondents and a written consent form was signed by the interviewers for documentation.

Study design and setting

This study was a prospective longitudinal survey of 209 women of reproductive age 18 – 49 years who received the LNG IUS as a method of choice after undergoing counseling using the Balanced Counselling Strategy (BCS) for FP. The study was conducted in 40 select private health clinics that are members of the SFH Healthy Family Network (HFN), a social franchise of private health facilities. The 40 selected facilities had high numbers of clientele with IUDs and are implementing service delivery for LNG IUS under the Supporting International Family Planning Organisation (SIFPO) Project, which provided the IUS method in the context of informed choice using the ICA Foundation donated LNG IUS product. The facilities are in 17 states in Nigeria, namely Abia, Akwa Ibom, Cross River, Enugu, Rivers, Kano, Katsina, Imo, Gombe, Taraba, Lagos, Ogun, Oyo, Benue, Niger, Edo, and the Federal Capital Territory (FCT) where the franchise operates.

Participant selection

Trained health providers in the facilities recruited consenting women who already accepted the IUS as their method of choice to participate in a telephone interview. Only women aged 18 to 49 years were recruited. Recruited participants were contacted by trained call agents/interviewers at predetermined periods: at two weeks post-insertion of the IUS in the facility, at three months, and after 12 months. Women who consented and agreed for their phone number to be passed on to the research team were contacted for interviews and follow-up. Only their first names and phone numbers were passed to the research team via SMS. The SMS was immediately deleted from the provider's phones after receipt from the research team. Women less than 18 years of age were excluded from this study. Confidentiality of the respondent's information was ensured by assigning unique identification codes to each recruited participant, and all respondents' data were electronically stored, and the files were password protected. The sample size calculation for the study was based on the following formula:

$$N = \frac{\left[Z_{1-\alpha}\sqrt{2p(100-p)} + Z_{1-\beta}\sqrt{p_1(100-p_1)+p_2(100-p_2)}\right]^2}{(p_2-p_1)^2}$$

Where N is the sample size, P1 (proportion of the sample reporting satisfaction at time 1) = 75%, P2 (proportion of the sample reporting satisfaction at time 2) = 60%, Z1- α is the standard normal deviate corresponding to a two-sided level of significance (α) of 5%, Z1-β (statistical power) = 0.8. The initial calculated sample size was 135 considering a design effect of 1.2. The final sample of 208 was recruited with the consideration of about 45% loss-to-follow-up rate between baseline and the 12-month follow-up.

Data collection

Women were considered as loss-to-follow up if they could not be reached after at least five repeated attempts within a couple of days. The loss-to-follow-up was mainly due to non-reachable phone contacts after five repeated attempts and due to women refusing interviews during the follow-up. No form of incentive was given to participants in the study. Baseline data collection started in May 2017 and lasted for about 8 months until the required sample was achieved. Subsequent follow-up interviews were done on a date scheduled with the participant at three months and 12 months. Data collection, therefore, ended in 2018 after the last scheduled 12-month interview. Data were collected electronically using a questionnaire implemented on the ODK android software. The ODK is a computer-assisted personal interview (CAPI) application available for Android devices for electronic data collection.

Information was collected on the respondent's background characteristics and their FP use experience, which included

pregnancy intention, the occasion for the insertion of the IUS such as miscarriage or abortion, side effects (experienced during the use of IUS at three months and 12 months) and complaints of discomfort from the IUS string by her partner. The women were also asked about how satisfied they were with using the IUS, and if they would recommend the IUS to other women or a friend. A Likert scale was used to score the responses of the women to the satisfaction question. The Likert scale ranged from 1–5, with an increasing score indicating increasing satisfaction with the method. User satisfaction response was re-coded such that a respondent's score of 1–3 indicated no satisfaction, while scores of 4–5 indicated satisfaction with the method. Continuation rate was measured as the proportion of women who received the IUS and reported they are still using the method at the time of the three-month and 12-month follow-up surveys.

Statistical analysis

Data was presented in this study using descriptive statistics with frequencies, percentages, and 95% confidence intervals as appropriate. Association between independent variables of background characteristics and FP/ IUS experiences with the dependent variables (continuation of the IUS and satisfaction) were tested using the Chi-square test. Statistical significance for association was set at $p<0.05$. Given the attrition recorded in the survey, possible attrition bias was examined by carrying out a Chi-square test to compare the background characteristics between those who were reached in the second and third rounds of the study with those who were not reached. Statistically significant differences in the background characteristics between those reached and those not reached would indicate some existence of attrition bias in the result estimates. Data analysis was done using IBM SPSS Statistics - version 25.

Results

User background characteristics, FP and IUS use experiences

A total of 208 users were interviewed at baseline. At the three-month follow-up, 98 women were successfully reached and interviewed, while at the 12-month follow-up, 73 women were successfully reached and interviewed. The average age of users of the IUS in the study at baseline was 33.7±6, and the majority age group was 35 years and older (44.2%), while approximately 30% and 20% of the users were aged between 30–34 years and 25–29 years old, respectively. More than half of users had between 1–3 children (58.2%), another good proportion, 38.5%, had 4–7 children, and very few users had no children (1.4%) (Table 1). The Chi-square test results in Table 1 showed statistical significance for only age at 3-month for the sample due to the attrition. For all other background characteristics, no statistical significance was observed in the background characteristics of the participants reached and those not reached in the follow-up surveys. Nearly a third of the women in the study reported they were no longer seeking pregnancy (31.7%), while another 23.6% said they would seek a pregnancy in the next 3–5 years, and 10% said in the next 1–2 years.

Around 4% reported receiving the IUS two weeks before carrying out an abortion or after a miscarriage. Up to 96.2% of users of the method reported they were satisfied with getting the IUS inserted at the clinic at the uptake of the method. Table 2 presents more of the IUS use experiences and characteristics of the participants.

The most common side effects were less or no bleeding, irregular bleeding, and breast tenderness/pain. Reports of less bleeding increased from 8.2% at three months to 24.7% at 12 months, while irregular bleeding which was high at 3 months (32.7%) reduced to 4.1% at 12 months. The prevalence of other side effects during the use of the IUS at three months and 12 months are presented in Table 3.

Some of the reasons for discontinuation of the IUS at 12 months were mainly due to experience of decreased menstrual bleeding or amenorrhea (25%), pain (18%), and weight gain (12%). Other reasons were as a result of worry of being pregnant because of no bleeding (6.3%) and partner complaining about feeling the strings of the IUS (16.7) (see Figure 1).

Concerning recommending the benefits of the IUS, a high rate for a recommendation of the benefits of the IUS were seen for attributes such as its fewer sides effects (23.4% at 3 months and 14.4% at 12 months) and its convenience of use (21.9% at 3 months and 15.1% at 12 months). Other reported high reasons for recommending the IUS were its high effectiveness, long duration of effectiveness, reduced bleeding, and affordability of the product at the facility (Table 4).

Rates of continuation and user satisfaction with the IUS

Of the 98 women who were interviewed at three months post-insertion of their IUS, 96.9% (95% CI: 91.3, 99.3) of them were still using the method, while at 12 months post-insertion, 91.8% (95% CI: 82.9, 96.9) of the 73 women reached reported still using the IUS method. The proportion of users who were satisfied with the method at baseline at two weeks post-uptake was 95.2% (95% CI: 91.3, 97.6), while satisfaction with the method at three months and 12 months post-uptake was 76.5% (95% CI: 66.8, 84.5) and 86.3% (95% CI: 77.5, 94.1), respectively.

Continuation and satisfaction with IUS according to user characteristics and experiences

Our analysis showed that continuation of IUS at 12 months was significantly lower (83.8%) among women who visited a provider because of problems with the method than women who did not visit a provider (100%). Analyses were also conducted to see if continuation was correlated with age, fertility intention, counseling, etc. but none of these were found to be statistically significant. In addition to the higher rate of uptake among older women, the continuation rate at 12 months was higher among older women of ages 30 years and older, ranging from about 92% to about 97%, compared with those aged 25 – 29 years old, which was about 80% (Table 5). According to marital status, high rates for the continuation of the IUS

Table 1. Baseline demographic characteristics of users of levonorgestrel intrauterine system and the assessment of attrition in the follow-up surveys.

Background characteristics	Survey at baseline	Survey at 3 months follow-up			Survey at 12 months follow-up		
		Dropped out	Participated	X^2 (p)	Dropped out	Participated	X^2 (p)
	n (%)	n (%)	n (%)		n (%)	n (%)	
Age category							
18–24 years old	12 (5.8)	11 (91.7)	1 (8.3)	7.906 (0.048)	11 (91.7)	1 (8.3)	5.975 (0.113)
25 – 29 years old	42 (20.2)	21 (50.0)	21 (50.0)		27 (64.3)	15 (35.7)	
30 – 34 years old	62 (29.8)	30 (48.4)	32 (51.6)		35 (56.5)	27 (43.5)	
35 and older	92 (44.2)	48 (52.2)	44 (47.8)		62 (67.4)	30 (32.6)	
Highest level of schooling							
Never attended school	2 (1.0)	1 (50.0)	1 (50.0)	5.099 (0.165)	2 (100.0)	0 (0.0)	3.783 (0.286)
Attended but did not complete school	4 (1.9)	4 (100.0)	0 (0.0)		4 (100.0)	0 (0.0)	
Primary	16 (7.7)	6 (37.5)	10 (62.5)		9 (56.2)	7 (43.8)	
Secondary or higher	186 (89.4)	99 (53.2)	87 (46.8)		120 (64.5)	66 (35.5)	
Marital status							
Single	3 (1.4)	3 (100.0)	0 (0.0)	3.836 (0.280)	3 (100.0)	0 (0.0)	3.929 (0.269)
Married/living together	198 (95.2)	102 (51.5)	96 (48.5)		126 (63.6)	72 (36.4)	
Widowed	3 (1.4)	2 (66.7)	1 (33.3)		2 (66.7)	1 (33.3)	
Divorced/separated	4 (1.9)	3 (75.0)	1 (25.0)		4 (100.0)	0 (0.0)	
Religion							
Islam	37 (17.8)	23 (62.2)	14 (37.8)	3.846 (0.146)	28 (75.7)	9 (24.3)	5.363 (0.068)
Christian (non-Catholic)	151 (72.6)	80 (53.0)	71 (47.0)		98 (64.9)	53 (35.1)	
Christian (Catholic)	20 (9.6)	7 (35.0)	13 (65.0)		9 (45.0)	11 (55.0)	
Parity							
0	3 (1.4)	3 (100.0)	0 (0.0)	5.133 (0.162)	3 (100.0)	0 (0.0)	2.098 (0.552)
1–3	121 (58.2)	60 (49.6)	61 (50.4)		76 (62.8)	45 (37.2)	
4–7	80 (38.5)	46 (57.5)	34 (42.5)		53 (66.2)	27 (33.8)	
8 and more	4 (1.9)	1 (25.0)	3 (75.0)		3 (75.0)	1 (25.0)	
Age of youngest child							
Less than 1 year old	75 (36.6)	40 (53.3)	35 (46.7)	4.138 (0.126)	47 (62.7)	28 (37.3)	3.416 (0.181)
1–5 years	104 (50.7)	49 (47.1)	55 (52.9)		64 (61.5)	40 (38.5)	
6 years and above	26 (12.7)	18 (69.2)	8 (30.8)		21 (80.8)	5 (19.2)	
Total	**208 (100.0)**	**107 (52.2)**	**98 (47.8)**		**135 (64.9)**	**73 (35.1)**	

were seen at three and 12 months post-insertion among women living with their partner, which was 96.8% at 3 months and 91.7% at 12 months. As there were not enough single women in the study, the continuation rate among this group was not

Table 2. **Family planning and experiences of levonorgestrel intrauterine system (IUS) use.**

	Frequency	Percent
Pregnancy intention (baseline)		
In less than a year	1	0.5
In 1–2 years	21	10.1
In 3–5 years	49	23.6
In more than 5 years	12	5.8
Never	66	31.7
Do not know	59	28.4
Receiving IUS within two weeks of having an abortion or miscarriage (baseline)		
Yes	8	3.8
No	200	96.2
Satisfaction in getting the IUS inserted (baseline)		
Yes	200	96.2
No	8	3.8
Impact of not bleeding to wellbeing at 12-month		
Positive	5	27.8
Negative	7	38.9
Neutral	6	33.3
Partner feels IUS strings at 12 months		
Yes	18	24.7
No	53	72.6
Not sure	2	2.7
Counselling at uptake about what to do if side-effect is experienced (baseline)		
Yes	68	32.5
No	135	64.9
Do not know	5	2.4
Visits to provider because of problem with method at 12 months		
Yes	37	50.7
No	36	49.3
Likelihood of recommending the IUS at 12 weeks post insertion		
Would recommend	200	96.2
Would not recommend	2	1.0
Not sure	6	2.9
Likelihood of recommending the IUS at 12 weeks post insertion		
Would recommend	65	89.0
Would not recommend	0	0
Not sure	8	11.0
Alternative method on switching from LNG IUS at 12 months		
No method/ pregnant	5	83.3
Pills	1	16.7

Table 3. Prevalence of side-effects of the IUS at 3- and 12-month post insertion.

Side effects		Prevalence with method at 3 months	Prevalence with method at 12 months
		n (%)	n (%)
Less bleeding	No	90 (91.8)	55 (75.3)
	Yes	8 (8.2)	18 (24.7)
No bleeding	No	92 (93.9)	48 (65.8)
	Yes	6 (6.1)	25 (34.2)
Irregular bleeding	No	66 (67.3)	70 (95.9)
	Yes	32 (32.7)	3 (4.1)
Vaginal bacterial infections	No	96 (98.0)	72 (98.6)
	Yes	2 (2.0)	1 (1.4)
Acne	No	98 (100)	69 (94.5)
	Yes	0 (0.0)	4 (5.5)
Headache/migraine	No	95 (96.9)	100 (100)
	Yes	3 (3.1)	0 (0.0)
Nausea	No	98 (100)	73 (100)
	Yes	0 (0)	0 (0.0)
Pain during sex	No	98 (100)	68 (93.2)
	Yes	0 (0.0)	5 (6.8)
Abdominal discomfort/pain	No	88 (89.8)	69 (94.5)
	Yes	10 (10.2)	4 (5.5)
Breast tenderness/pain	No	97 (99.0)	65 (89.0)
	Yes	1 (1.0)	8 (11.0)
Pelvic discomfort/pain	No	94 (95.9)	73 (100)
	Yes	4 (4.1)	0 (0.0)
Depression	No	98 (100)	69 (94.5)
	Yes	0 (0.0)	4 (5.5)
Mood changes	No	98 (100)	58 (71.2)
	Yes	0 (0.0)	15 (20.5)

*Includes continuers and discontinuers.

presented. Continuation of the use of IUS based on fertility intention was varied among users but higher among users who intended to get pregnant after three years than those intending to become pregnant in under 3 years; this was, also not significant ($p>0.05$). Counseling on side effects was also not statistically associated with continuation of IUS, although more women who received counseling on side effects (95.5%) than those who did not receive counseling (90%) continued the use of the IUS at 12 months.

Concerning the relationship between satisfaction with method and women's characteristics (Table 6), our result showed that

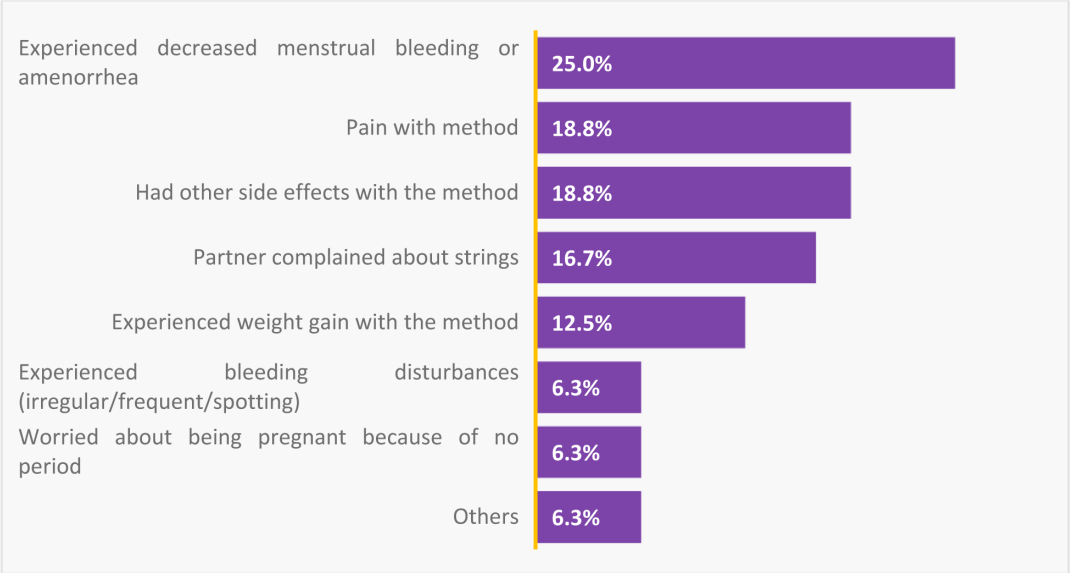

Figure 1. Percentages for reasons for discontinuation of levonorgestrel intrauterine system (LNG IUS) at 12 months post-insertion.

Table 4. Recommended benefits of the levonorgestrel intrauterine system (LGN IUS) at three months and 12-month post-insertion.

Benefits of IUS recommended	Participant responses at 3 months post-insertion		Participant responses at 12 months post-insertion	
	n	% response	n	% response
Lasts for a long time	43	12.9	-	-
Convenience: once in place nothing else on a regular basis is needed to be done	73	21.9	22	15.1
Discrete: nobody else will know about use	19	5.7	5	3.4
Fewer side effects compared with other methods	79	23.4	21	14.4
Highly effective	78	23.4	48	32.9
Reduced menstrual bleeding	15	4.5	16	11.0
Reversible: possibility of conception in the future	22	6.6	14	9.6
OK for breastfeeding; convenience	2	0.6	6	4.1
Expensive elsewhere and more affordable now	1	0.0	1	0.7
Others	1	0.3	13	8.9

a significantly higher proportion of women, at 12 months, who did not visit a provider because of problems with the method (97.2%) were satisfied with the method compared with those who visited a provider (approximately 76%). This association also showed statistical significance a 3-months post-insertion. Satisfaction was significantly associated with religious affiliation at 3 months. We found significantly higher satisfaction ($p<0.05$) with the use of the IUS among users who did not

Table 5. Socio-demographic, family planning and levonorgestrel intrauterine system (LNG IUS) experiences by continuation of the LNG IUS.

User Characteristics	3 months post insertion				12 months post insertion			
	Yes	No	Total	$X^2(p)$	Yes	No	Total	$X^2(p)$
	n (%)	n (%)			n (%)	n (%)		
Age category (baseline)								
18–24 years old	1 (100.0)	0 (0.0)	1	2.722 (0.436)	1 (100.0)	0 (0.0)	1	3.822 (0.281)
25 – 29 years old	20 (95.2)	1 (4.8)	21		12 (80.0)	3 (20.0)	15	
30 – 34 years old	30 (93.8)	2 (6.2)	32		25 (92.6)	2 (7.4)	27	
35 and older	44 (100.0)	0 (0.0)	44		29 (96.7)	1 (3.3)	30	
Level of schooling (baseline)								
Never attended school	1(100.0)	0 (0.0)	1	1.824 (0.402)	-	-		
Attended but did not complete school					-	-		
Primary	9(90.0)	1 (10.0)	10		7 (100)	0 (0.0)	7	0.693 (0.405)
Secondary or higher	85 (97.7)	2 (2.3)	87		60 (90.9)	6 (9.1)	66	
Marital status (baseline)								
Single	-	-			-	-	-	
Married/living together	93 (96.8)	3 (3.1)	96	0.064 (0.968)	66 (91.7)	6 (8.3)	72	0.091 (0.763)
Widowed	1 (100)	0 (0.0)	1		1 (100)	0 (0.0)	1	
Divorced/separated	1 (100)	0 (0.0)	1					
Religion (baseline)								
Islam	13 (92.9)	1 (7.1)	14	1.211 (0.546)	8 (88.9)	1 (11.1)	9	0.143 (0.931)
Christian (non-Catholic)	69 (97.2)	2 (2.8)	71		49 (92.5)	4 (7.5)	53	
Christian (Catholic)	13 (100)	0 (0.0)	13		10 (100)	0 (0.0)	10	
Parity (baseline)								
0	0	0	0		-	-	-	
1	7 (100)	0 (0.0)	7	0.326 (0.955)	4 (66.7)	2 (33.3)	6	7.224 (0.065)
2	28 (96.6)	0 (3.4)	29		19 (95.0)	1 (5.0)	20	
3	24 (96.0)	1 (4.0)	25		19 (100)	0 (0.0)	19	
4 and more	36 (97.3)	1 (2.7)	37		25 (89.3)	3 (10.7)	28	
Age of youngest child (baseline)								
0 year	34 (97.1)	1 (2.9)	35	0.319 (0.853)	26 (92.9)	2 (7.1)	28	0.659 (0.719)
1–5 years	53 (96.4)	2 (3.6)	55		36 (90.0)	4 (10.0)	41	
6 years and above	8 (100)	0 (0.0)	8		5 (100.0)	0 (0.0)	5	
Pregnancy intention (baseline)								

User Characteristics	3 months post insertion				12 months post insertion			
	Yes	No	Total	$X^2(p)$	Yes	No	Total	$X^2(p)$
	n (%)	n (%)			n (%)	n (%)		
In less than a year	-	-	-		-	-	-	
In 1–2 years	11 (100)	0 (0.0)	11	2.930 (0.570)	8 (88.9)	1 (11.1)	9	1.973 (0.741)
In 3–5 years	21 (95.5)	1 (4.5)	22		16 (94.1)	1 (5.9)	17	
In more than 5 years	5 (100)	0 (0.0)	5		3 (100.0)	0 (0.0)	3	
Do not know	30 (100)	0 (0.0)	30		22 (95.7)	1 (4.3)	23	
(Never)	28 (93.3)	2 (6.7)	30		18 (85.7)	3 (14.3)	21	
Receiving IUS within 2 weeks of having an abortion or miscarriage								
Yes	2 (100)	0 (0.0)	2	0.064 (0.800)	1 (100.0)	0 (0.0)	1	0.091 (0.763)
No	93 (96.9)	3 (3.1)	96		66 (91.7)	6 (8.3)	72	
Impact of not bleeding to wellbeing[#]								
Positive	-	-	-	-	5 (100.0)	0 (0.0)	5	1.714 (0.424)
Negative	-	-	-	-	5 (71.4)	2 (28.6)	7	
Neutral	-	-	-	-	5 (83.3)	1 (16.7)	6	
Partner feels IUS strings								
Yes	-	-	-	-	17 (94.5)	1 (5.6)	18	0.572 (0.751)
No	-	-	-	-	47 (90.4)	5 (9.6)	52	
Do not know	-	-	-	-	3 (100)	0 (0.0)	3	
Counselling at uptake about what to do if side-effect is experienced								
Yes	33 (97.1)	1 (2.9)	34	0.036 (0.982)	21 (95.5)	1 (4.5)	22	0.693 (0.707)
No	61 (96.8)	2 (3.2)	63		45 (90.0)	5 (10.0)	50	
Do not know	1 (100)	0 (0.0)	1		1 (100)	0 (0.0)	1	
Visits to provider because of problem with method								
Yes	19 (100)	0 (0)	19	0.315 (0.574)	31 (83.8)	6 (16.2)	37	6.361 (0.012)
No	60 (98.4)	1 (1.6)	61		36 (100.0)	0 (0.0)	36	
Total	**95 (96.9)**	**3 (3.1)**			**67 (91.8)**	**6 (8.2)**		

#Among participants who experienced no bleeding.

report vaginal bacterial infection (87.5% satisfied) during the assessment at 12 months. The only case in the sample who reported vaginal infection did not report satisfaction with the method. Not experiencing breast tenderness or pain (90.8%) and not experiencing acne (88.4%) were also associated with satisfaction with the IUS, compared with experiencing breast tenderness and acne (50% each) with IUS use during the assessment at 12 months post-uptake (Table 7).

Table 6. **Socio-demographic, family planning and levonorgestrel intrauterine system (LNG IUS) experiences by satisfaction with the LNG IUS use.**

User Characteristics	2 weeks post-insertion (Baseline)				3 months post-insertion*				12 months post-insertion*			
	Not satisfied	Satisfied	Total	$X^2(p)$	Not satisfied	Satisfied	Total	$X^2(p)$	Not satisfied	Satisfied	Total	$X^2(p)$
	n (%)	n (%)			n (%)	n (%)			n (%)	n (%)		
Age category (baseline)												
18-24 years old	0(0)	12(100)	12	1.592 (0.661)	0 (0.0)	1(100)	1	0.634 (0.889)	0(0.0)	1(100.0)	1	1.038 (0.792)
25 - 29 years old	1(2.4)	41(97.6)	42		4 (19.0)	17 (81.0)	21		3 (18.8)	12 (80.0)	15	
30 - 34 years old	4(6.5)	58(93.5)	62		8 (25.0)	24 (75.0)	32		4 (15.4)	23 (85.2)	27	
35 and older	5(5.4)	87(94.6)	92		11 (25.0)	33 (75.0)	44		3 (10)	27 (90.0)	30	
Level of schooling (baseline)												
Never attended school	0(0.0)	2(100)	2	3.842 (0.279)	0 (0.0)	1(100)	1	3.800 (0.150)	-	-	-	
Attended but did not complete school	1(25.0)	3(75.0)	4		-	-	-		-	-	-	
Primary	1(6.2)	15(93.8)	16		0 (0.0)	10 (100)	10		1 (14.3)	6 (85.7)	7	0.002 (0.962)
Secondary or higher	8(4.3)	178 (95.7)	186		23 (26.4)	64 (73.6)	87		9 (13.8)	57 (86.4)	66	
Marital status (baseline)												
Single	0 (0.0)	3(100)	3	5.717 (0.126)	-	-	-	0.626 (0.731)	-	-	-	
Married/living together	9 (4.5)	189 (95.5)	198		23 (24.0)	73 (76.0)	96		10 (13.9)	62 (86.1)	72	0.161 (0.688)
Widowed	1 (33.3)	2 (66.7)	3		0 (0.0)	1 (100.0)	1		0 (0.0)	1(10.00)	1	
Divorced/separated	0 (0.0)	4 (100)	4		0 (0.0)	1 (100.0)	1		-	-	-	
Religion (baseline)												
Islam	1 (2.7)	36 (97.3)	37	1.546 (0.462)	2 (14.3)	12 (85.7)	15	6.119 (0.047)	2 (20.0)	7 (77.8)	9	0.761 (0.683)
Christian (non-Catholic)	7 (4.6)	144 (95.4)	151		21 (29.6)	50 (70.4)	71		7 (13.5)	46 (86.5)	53	
Christian (Catholic)	2 (10)	18 (90)	20		0 (0.0)	13 (100.0)	13		1 (10)	10 (90)	11	

User Characteristics	2 weeks post-insertion (Baseline)				3 months post-insertion*				12 months post-insertion*			
	Not satisfied	Satisfied	Total	$X^2(p)$	Not satisfied	Satisfied	Total	$X^2(p)$	Not satisfied	Satisfied	Total	$X^2(p)$
	n (%)	n (%)			n (%)	n (%)			n (%)	n (%)		
Parity (baseline)												
0	1 (33.3)	2(66.7)	3	8.488 (0.075)	-	-	-	3.822 (0.281)	-	-	-	3.983 (0.263)
1	2 (12.5)	14 (87.5)	16		1 (16.7)	6 (85.7)	7		2 (40.0)	4 (66.7)	6	
2	3 (5.3)	54 (94.7)	57		7 (24.1)	22 (75.9)	29		4 (19.0)	16 (80)	20	
3	1 (2.1)	47 (97.9)	48		3 (12.0)	22 (88.0)	25		1 (5.3)	18 (94.7)	19	
4 and more	3 (3.6)	81 (96.4)	84		12 (32.4)	25 (67.6)	37		3 (10.7)	25 (89.3)	28	
Age of youngest child (baseline)												
0 year	3 (4)	72 (96.0)	75	0.089 (0.957)	6 (17.6)	29 (82.9)	35	2.284 (0.319)	3 (11.1)	24 (88.9)	27	0.372 (0.830)
1–5 years	5 (4.8)	99 (95.2)	104		16 (29.1)	39 (70.9)	55		6 (15.0)	35 (85.0)	40	
6 years and above	1(3.8)	25 (96.2)	26		1 (12.5)	7 (87.5)	8		1(20)	4 (80.0)	5	
Pregnancy intention (baseline)												
In less than a year	0(0.0)	1 (100.0)	1	10.732 (0.057)	-	-	-		-	-	-	
In 1–2 years	4 (19.0)	17 (81.0)	21		1 (10.0)	10 (90.9)	11	6.659 (0.155)	2 (25.0)	7 (77.8)	9	2.937 (0.568)
In 3–5 years	2 (4.1)	47 (95.9)	49		6 (27.3)	16 (72.7)	22		3 (17.6)	14 (82.4)	17	
In more than 5 years	0 (0.0)	12 (100)	12		0 (0.0)	5 (100)	5		0 (0.0)	3 (100)	3	
Never	2 (3.0)	64 (97.0)	66		5 (16.7)	25 (83.3)	30		4 (17.4)	19 (82.6)	23	
Do not know	2 (3.4)	57(96.6)	59		11 (36.7)	19 (63.3)	30		1(4.8)	20 (95.2)	21	
Receiving LNG IUS within 2 weeks of having an abortion or miscarriage (Baseline)												
Yes	2 (25.0)	6 (75.0)	8	7.412 (0.006)	1 (50.0)	1(50.0)	2	0.800 (0.371)	0 (0.0)	1(100.0)	1	0.161 (0.688)
No	8 (4.0)	192 (96.0)	200		22 (22.9)	74 (77.1)	96		10 (14.1)	62 (86.1)	72	
Impact of not bleeding to wellbeing#												
Positive	-	-	-	-	-	-	-	-	0 (0.0)	5 (100.0)	5	1.714 (0.424)
Negative	-	-	-	-	-	-	-	-	2 (28.6)	5 (71.4)	7	
Neutral	-	-	-	-	-	-	-	-	1 (16.7)	5 (83.3)	6	

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User Characteristics	2 weeks post-insertion (Baseline)				3 months post-insertion*				12 months post-insertion*			
	Not satisfied	Satisfied	Total	$X^2(p)$	Not satisfied	Satisfied	Total	$X^2(p)$	Not satisfied	Satisfied	Total	$X^2(p)$
	n (%)	n (%)			n (%)	n (%)			n (%)	n (%)		
Partner feels IUS strings												
Yes	-	-	-	-	-	-	-	-	3 (16.7)	15 (83.3)	18	0.613 (0.736)
No	-	-	-	-	-	-	-	-	7(12.3)	45 (86.5)	52	
Do not know	-	-	-	-	-	-	-	-	0 (0)	3 (100.0)	3	
Counselling at uptake about what to do if side-effect is experienced												
Yes	3 (4.4)	65 (95.6)	68	0.318 (0.853)	5 (14.7)	29 (85.3)	34	2.673 (0.263)	1 (4.5)	21 (95.5)	22	2.500 (0.286)
No	7 (5.1)	128 (94.8)	135		18 (28.6)	45 (71.4)	63		9 (18.4)	41 (81.6)	50	
Do not know	0 (0.0)	5 (100)	5		0 (0.0)	1 (100)	1		0 (0.0)	1 (100.0)	1	
Visits to provider because of problem with method												
Yes	-	-	-	-	3 (17.6)	14 (82.4)	17	7.002 (0.008)	9 (24.3)	28 (75.7)	37	7.165 (0.007)
No	-	-	-	-	1 (1.6)	60 (98.4)	61		1 (2.8)	35 (97.2)	36	
Total (N)	**10 (4.8)**	**198 (95.2)**	**208**		**23 (23.5)**	**75 (76.5)**	**98**		**10 (13.7)**	**63 (86.3)**	**73**	

*Includes continuers and discontinuers.

#Among participants who experienced no bleeding.

Table 7. Satisfaction with levonorgestrel intrauterine system according to experience of side effects at 12-month post-insertion.

Side effects		Satisfaction with method at 12 months*				
		% Not satisfied	% satisfied	Total	X^2	*p*-value
Less bleeding	No	12.7	87.3	55	0.178	0.673
	Yes	16.7	83.3	18		
No bleeding	No	10.4	89.6	48	1.277	0.258
	Yes	20.0	80.0	25		
Irregular bleeding	No	14.3	85.7	70	0.497	0.481
	Yes	0.0	100.0	3		
Vaginal bacterial infections	No	12.5	87.5	72	6.388	0.011
	Yes	100.0	0.0	1		
Acne	No	11.6	88.4	69	4.717	0.030
	Yes	50.0	50.0	4		
Pain during sex	No	13.2	86.8	68	0.180	0.671
	Yes	20.0	80.0	5		
Abdominal discomfort/pain	No	14.5	85.5	69	0.672	0.412
	Yes	0.0	100	4		
Breast tenderness/pain	No	9.2	90.8	59	10.015	0.002
	Yes	50.0	50.0	4		
Depression	No	14.5	85.5	69	0.672	0.412
	Yes	0.0	100.0	4		
Mood changes	No	17.2	82.5	58	2.997	0.083
	Yes	0.0	100.0	15		

*Includes continuers and discontinuers.

Association analysis between satisfaction with age, the impact of bleeding, pregnancy intention, counseling (Table 6), and side effects like less bleeding, no bleeding, or irregular bleeding (Table 7), were not statistically significant. The findings showed varied high satisfaction with the IUS according to age groupings but were not statistically associated at three months and 12 months post-uptake (Table 6). Satisfaction with the IUS at 12 months post-insertion was markedly higher among women who reported a positive impact of not bleeding from the use of the IUS, compared with those who reported a negative impact of not bleeding, although this was not statistically significant. With regards to pregnancy intention at 12 months post-up-take, women who reported having an intention to get pregnant in the next 3 years and above showed higher satisfaction (range between 82% – 100%) than those who reported having an intention to get pregnant at 2 years (77.8%), this association was not statistically significant.

Experience of satisfaction with the method at 12 months post-uptake was lower among women experiencing less bleeding (83.3%) than women not experiencing less bleeding (87.3%). Similarly, satisfaction was lower with the experience of no bleeding (80%) in contrast to the experience of bleeding (89.6%); these findings on the association between the bleeding changes and satisfaction, were, however, not statistically significant ($p>0.05$).

Discussion

In our study, we found high continuation rates and satisfaction with the hormonal IUD among the users. During the use of contraception, adherence to the method is very important for the prevention of unintended pregnancies, as such the high continuation rate of the IUS contraceptive in our study is indicative of the method's potential and acceptability to reduce the high risk of unwanted and unplanned pregnancies among women

who genuinely need to continue contraception. Similar high continuation rates of the IUS in the first 12 months of use have been reported in previous studies[12,19]. The IUS has been reported to be highly effective and very tolerable, making the method very acceptable. Side effects are fewer and less serious, which is likely to influence the user's likelihood of satisfaction with and continuation of the method. As our study showed, the majority of the women were satisfied with the IUS, and this satisfaction is correlated to their lowered experience with side effects. Satisfaction from the IUS can also be related to its convenience (in the sense that once the method is inserted, nothing else regularly is needed to be done), as we found that this was among the major reasons the IUS was recommended to other potential FP users.

Experiencing no bleeding or less bleeding, which is a characteristic of the hormonal IUD, presented lower satisfaction (although not statistically significant) with the LNG IUS in our study, compared with other studies where women who experienced amenorrhea tend to appreciate more of this characteristic of the IUS method[20]. The reason for our findings may not be unconnected to the socio-cultural norms and beliefs that exist in the society about menstruation. Several studies have reported on the misconceptions and myths about menstruation, citing that some women believe menstruation to be a result of the body system discharging unwanted 'bad blood' from the body[21,22]. This assertion reasonably supports our findings for the lowered satisfaction with the method resulting from reduced or lack of menstrual bleeding. Conversely, we found that most women reporting a negative impact of non-bleeding due to the IUS were less satisfied. Our finding that older women (≥35 years) and women with more children (≥2 children) presented higher proportion to continue the use of the IUS, compared with their younger counterparts and women with fewer children (≤1 child), was not surprising. Several studies have also reported high continuation with LARC among women with more children[23,24]. Clinicians should encourage younger women and women with fewer children to use LARC as long as they need to delay pregnancies.

Adequate counseling and visiting a health provider for the uptake of health services has been linked with adherence to the use of the health service and of FP specifically[25,26]. This is important because patients/clients receive relevant information, access check-ups, and get informed about potential risks, fears, and misunderstandings that might exist and can affect the continuation of health services. We found in our study that more women who received counseling continued the use of the IUS than those who did not, this finding, however, was not statistically significant. Although women are free to discontinue the use of the method at any time, health providers offering support on the management of side effects and counseling on expectations of these side effects of the IUS may also have influenced the continuing use of the method that we observed. Previous studies have, however, reported provider bias in the uptake and use of FP methods to influence the choice of FP method[27,28]. Health providers, however, need to provide adequate information and counseling to clients to encourage optional use of an FP method to suit the client's FP needs.

A strength of this study is that the data collection approach via phone interview can be thought to have guaranteed less respondent bias on the disclosure of private information about FP use and contraceptives. The limitation of this study, however, is the high attrition rate. Analysis showed some significant difference in the data between the age of participants between baseline and at midline, but not end line of the study, indicating that there was no serious potential attrition bias. Further, while the sampling for this study was widespread and done from 40 facilities across 17 states in Nigeria, given the small sample size and selection of facilities only from the private sector, caution should be taken on the generalization of the findings regarding users of the hormonal IUD in other regions in the country or across the entire country. Further studies are required on the reproductive and health profiles of the users of the IUS in Nigeria with larger sample size and control to improve retention rate. A comparative study with other LARC methods will also provide further insights into the full potential of the IUS method. Evidence is also required on the use of the method in Nigeria for the treatment of menorrhagia and dysmenorrhea, which is quoted as a characteristic of the IUS method, to fully take advantage of these benefits.

Conclusion

In conclusion, the hormonal IUD has positive potential as an acceptable intrauterine contraceptive given the high continuation rate and user satisfaction with the method. The hormonal IUD method presents few side effects which influenced continuation and satisfaction with the method and makes it highly recommended to other potential users of contraceptives. National action is, therefore, recommended for expanding the availability of the hormonal intrauterine system method in the public and private sector to reduce the unmet need for family planning in Nigeria.

Data availability

Underlying data

Figshare: Continuation and user satisfaction of the levonorgestrel intrauterine system (LNG IUS) contraceptive in Nigeria, https://doi.org/10.6084/m9.figshare.12988313.v11[29].

Extended data

Figshare: Continuation and user satisfaction of the levonorgestrel intrauterine system (LNG IUS) contraceptive in Nigeria https://doi.org/10.6084/m9.figshare.12988313.v11[29].

This project contains the following extended data:

- Questionnaire and data codes_Continuation_user satisfaction of LNG IUS study

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Open Peer Review

Current Peer Review Status: ? ✓

Version 1

Reviewer Report 25 May 2023

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✓ **Gretchen S. Stuart**

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The authors present a very thorough description of the a longitudinal study to measure satisfaction of hormonal IUD in Nigeria. There are places where the paper could be more succinct, and this would help readers focus on the main points. Some examples:
Introduction - The introduction should be about 50% shorter - with a clear focus on the gaps in the literature and then final statements of what the specific objectives of this paper are.

Methods:
The methods are sound, and reproducible. There are places where grammar could be improved and sentences shorter to make it easier for readers to focus. The section on sample size can be shorter - there is no need for the formula to be described.

Results:
Overall the results are very long and repeat much of what is in the tables. Provide summary statements and refer readers to the tables.

Discussion:
The discussion is excellent, which is thoroughly comparing and contrasting to existing literature. There is also plenty of information about the importance of contraception and the IUD. Well done!

Tables:
The tables could be easier to read.
Table 1: This is baseline characteristics - so please consider only using the characteristics at enrollment. Round percentages so they are easier to read.
Table 2: use format N (%), this is easier to read.
Table 3: Column headings can be shorter with just 3 months, and 12 months because the table title description is thorough.

Table 4: Comments similar to Table 3, and use format n(%)
Tables 5& 6: These are too big and too confusing. Consider using a more descriptive title and selecting whether to present yes or no. And just present p-value.

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Yes

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Contraception, abortion,

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 16 May 2023

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Thank you for letting me review this interesting paper on the continuation and user satisfaction of the LNG-IUD in Nigeria. The article contributes to the field with results related to continued use in an LMIC setting, where the evidence is scarce, and shows high rates of continuation (91.8%) among participants that completed their follow-up.

A strength of the study is the prospective cohort design with a study population recruited at several clinics that aid in external validity. A limitation is the low rate of participation in the 12 month follow-up resulting in a loss of power in the presented results and a high attrition bias. Another limitation is the potential selection bias in the recruitment of patients, which has not been mentioned at all by the authors.

Specific comments:

1) Abstract:
Revise the abstract to reflect the revised manuscript. Also, the results section in the main text reports no method failure outcome.

2) Page three, left column, first paragraph:
"Sizable proportion"...as a service to the reader, please specify ranges in the referenced articles.

3) P3 left column, first paragraph:
last sentence is missing a full stop (.) in the end.

4) P3, right column, paragraph 3:
"However, the hormonal IUD does not contribute to the proportion of intrauterine contraceptives used by women10. In one study in Zaria Nigeria, of all the 1104 women who opted for an IUD as a method of contraception only 68 (6.1%) women chose the hormonal IUD11. This is in contrast to other countries; for example in the US, where the proportion of IUD users has been reported as 12%, with 74% of the users of the intrauterine contraceptives chosing the hormonal IUD12."

I consider this more part of the dicussion.

I have read the author instructions and I'm aware the main body text allowed is as much as 20000 words for original research, but I think the authors should keep the introduction more concise, and try to limit the length to approx 800-1000 words.

5) P3, right column, paragraph 4:
"The Mirena® LNG IUS that is produced by Bayer Healthcare Pharmaceuticals Inc is indicated to have an effective duration of up to 5 years. However, clinical trials suggest that the LNG IUS can provide contraceptive protection for up to 7 years15,16."

Mirena has received approval for up to 8 years use for contraception. Please revise.

6) P3, right column, paragraph 4:
Liletta also approved for 8 years of use for contraception (https://www.liletta.com/faqs)

7) P3, right column, paragraph 4:
Regards Eliora, given the same dosage as for liletta and mirena, the effectiveness should also be 8 years for contraception, however, the approval might still be limited to 5 years, consider rephrasing "having an effective duration" to "is approved for 5 years for contraception".

8) P4, left column, first paragraph:

"...effective methods such as the hormonal IUS"

The nomenclature is changing towards "hormonal intrauterine device, hormonal IUD" or LNG-IUD. ISBN 978-92-4-002173-0 .

The word LNG-IUS is no longer recommended. Please revise throughout the manuscript. NB, change also in the title.

9) P4, left column, first paragraph:
"...this study was therefore undertaken to..."

I think all types of original studies benefit from a clearly defined aim. I would suggest that you rephrase "this study was undertaken to..." to "the aim of this study was to assess..."

Also, please include the end time point for follow-up - I suppose that the aim is to assess and document the continuation of the LNG IUD at 12 months follow-up (primary outcome?)

When researchers review articles, we often use the word "aim" to see whether the results reflect the aim (and preferably research questions). Also, in systematic reviews, your article will be easier to find if you include a specified aim.

10) P4, Study design:
Please include a reference for the counseling method - BCS.

11) P4, study design:
"40 select private health clinics". Is this a typo? Should be 40 selected?

12) P4, study design:
Regards the ICA-provided LNG-IUD - is it always Mirena or all brands? Please clarify as the approved duration of use range from 5-8 years.

13) P4, Participant selection:
It says here *"trained"* health providers and call agents/interviewers. In what way were they trained? Please clarify.

14) P4, participant selection:
Critical issue - What's your primary outcome? Satisfaction at 3 months or 12 months? Previously, in the end of the introduction, you stated continuation of the IUD before you mentioned satisfaction with the method. You did not include at what time point. This needs to be clarified.

Also, for clarity, consider removing the formula and putting a more common power calculation statement. For example: "We hypothesized that 75% of the participants would be satisfied with their IUD at 6 months follow-up, with the corresponding figure being 60% at 12 months follow-up. To show this level of satisfaction with 80% power at a significance level of 0.05, we needed 135 participants. To allow for an estimated 45% loss to follow-up, the final sample size was set at 208 participants".

15) P4, data collection:
Were participants considered loss-to-FU at 3 months excluded from the attempts to collect 12 months data? Please clarify.

16) P4, data collection:
I would consider the incentive statement to suit better under the "Ethical statement" paragraph.

17) P5, Statistical analyses:
Later on, you will see comments about recommended logistic regression analyses. After revising the manuscript, if you choose to perform the recommended logistic regressions, please revise the statistical analysis section.

18) P5, Reults, left column, first paragraph:
Regards the proportion of women that had 4-7 children - although I interpret the word *"good proportion"* as though you imply that "a high proportion" of the participants had 4-7 children, I would suggest that you remove the word 'good' since it actually means that something is factually "fine" or "satisfactory".

19) P5, Results, left column, first paragraph:
Regards the chi-square test for attrition (Table 1). What's your interpretation of the results? The chi-square test performed is based on a 2x4 contingency table, and it seems like the youngest participants are the ones that have the highest follow-up rate at 3 months, whereas in the 12 months FU, the differences also among the 25-29-year-old and the 35 and older might differ?

Also, high attrition and significant differences found in characteristics should preferably be followed by some kind of sensitivity analysis and imputation for handling missing data. I'm aware that your study is not a randomised trial, however, you use the BCS as an intervention for counselling. Here is a reference (https://bmcmedresmethodol.biomedcentral.com/articles/10.1186/s12874-017-0442-1)

20) P5, Results - general comment on structure:
After the baseline characteristics, consider presenting the primary outcome first, followed by secondary outcomes.

Continuation rate at 3 and 12 months first, followed by side effects and reasons for discontinuation would be a logical order. Afterwards, you can present the benefits and reasons for recommending the IUS to a friend.

21) P5, results, Rates of continuation and user satisfaction with the IUS:
Given the high loss-to-follow-up rate, I think that you should include some kind of imputation of data (see comment above). You have the highest participation in follow-up among the youngest participants. Could you perform a calculation on the proportion of continued use in the different age groups, impute these proportions among drop-outs and see whether it affects the total continuation rate?

In many studies, discontinuation of the method of interest is a common reason for not participating in the follow-up. The participants think that they should no longer take part in the study as they no longer use the method and consider themselves as "not interesting".

22) P8, paragraphs below table 3:
"Concerning the relationship between satisfaction with method and women's characteristics..."

Associations between characteristics and the outcome should preferably be analysed in a logistic regression rather than with a chi-square test as multiple characteristics might correlate to each other.

23) page 15, left column, last sentence:
Regards the phrase *"This association was not statistically significant".* You have now, several times, stated that there are differences between participants followed by the phrase "not statistically significant". I would say this is false reporting, and readers might interpret your results in a way that there are differences when the analysis actually say there aren't. I would strongly suggest you only report the differences that are supported by a p-value less than 0.05, and leave out all "trends". You already have a much lower proportion of participants at follow-up than you anticipated and have lost your power in statistical analyses. In addition, I would recommend you do a **posthoc power calculation** based on the number of participants you reached and participated in the follow-up and add it to the beginning of the **results** section.

24) P16, left column, second paragraph, last sentence:
Before ending the sentence, consider including the words "...pregnancies, independent on the approved duration of use of the LNG IUD."

25) P16, left column, second paragraph:
"We found in our study that more women who received counseling continued the use of the IUS than those who did not, this finding, however, was not statistically significant."

Again, you refer to a difference but clarify that it is not statistically significant. Then there is no difference.

Also, in the methods section you state that you recruited patients opting for an IUD after receiving counseling following the balanced counselling strategy. Didn't all participants receive counseling? Please clarify. Could this possibly be that women who didn't receive counseling on potential side effects reported lower continued use (however, not statistically significant)?

26) Conclusion:
"The hormonal IUD method presents few side effects"

This statement is not reflecting the results presented in Table 7 with three side effects being statistically significant in relation to satisfaction. Please revise the conclusion.

27) Tables, general comment:
Reporting of X^2 values are redundant, p-value is enough.

28) Table 1:
I see a high risk of age-related correlations here. I suggest that Table 1 only includes information retrieved at baseline, and presented per age group, i.e. the columns being age groups. Then you

would much easier see the correlations.

Then, you can add another table showing the characteristics of those participating in the follow-up or not - or even easier, only present the characteristics that were statistically significantly associated with participating in the follow-up in text instead of in a table.

29) Table 1, parity and age of youngest child:
Parity - Change "8 and more" to "8 or more" and
Age of youngest child to "6 years or above"

30) Table 2:
The title doesn't really reflect the contents of the table. I would recommend the authors reflect upon what needs to be in a table and what could be presented in the text. In this table, I see pregnancy intention (would better fit in the baseline characteristics table), mixed with satisfaction, impact on wellbeing, partner feels strings (better in a side-effects table) etc.

31) Table 2:
"counselling at uptake about what to do if side-effect"...

What does this mean? That the participant *knows* what to do or that they received counselling? Please clarify.

32) Table 2:
"...likelihood of recommending the IUS".
There seem to be some typos here. Should the first be at 2 weeks post-insertion, and the second at 12 months? Now both rows say 12 weeks post-insertion.

33) Table 3:
Regards bleeding pattern.

Can you really have both less bleeding and no bleeding at a single time point? These types of errors usually occur when the question posed is not clear enough, or when the respondent can enter multiple responses. Consider collapsing these two rows and put an asterisk/symbol in the table as well as in the caption followed by an explanation of the reason for collapsing them.

34) Figure 1:
The total percentage exceeds 100%. Please include an explanation in the caption as to why this is. Could the participants report more than one reason?

35) Table 5:
"Counselling at uptake about what
to do if side-effect is experienced"

Again, what does this mean?

36) Table 6:
This table is not necessary and is hard to read (long). I suggest you remove it and present only the statistically significant characteristics and present them in the text, followed by a statement "No

other user characteristics were statistically significantly associated to satisfaction at the three different follow-up time points".

37) Table 7:
Merge the top cells on the right-hand side so that "satisfaction with method..." is in one cell.

Also, I have a problem seeing how the use of an IUD and experiencing a vaginal bacterial infection is related to satisfaction at 12 months? Is this a coincidence rather than an actual association? To my knowledge, there are no correlations between LNG-IUD use and vaginal bacterial infections?

The chi-square test you have done here only present the differences in the proportion of women reporting satisfaction and the occurrence of side effect and not the actual association. For that, you need to make another logistic regression adjusting for potential confounders.

Is the work clearly and accurately presented and does it cite the current literature?
Partly

Is the study design appropriate and is the work technically sound?
Partly

Are sufficient details of methods and analysis provided to allow replication by others?
Partly

If applicable, is the statistical analysis and its interpretation appropriate?
Partly

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Partly

Competing Interests: Personal fees from Bayer Sweden AB, for educational activities. Honorarium from Medsphere Corp USA, for expert opinions on LARC in Europe. I confirm that these potential conflicts of interest did not affect my ability to write an objective and unbiased review of the article.

Reviewer Expertise: long-acting reversible contraception, contraceptive counseling, emergency contraception, abortion

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.