Preventing unintended pregnancy among young women in Kenya: prospective cohort study to offer contraceptive implants

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Abstract

Background

Subdermal contraceptive implants have low discontinuation rates but are underused among young women in Africa. This study aimed to isolate the role initial contraceptive method has on preventing unintended pregnancy.

Study Design

We recruited 399 Kenyan women aged 18-24 years into a prospective cohort study if they wanted short-acting hormonal methods (injectable or oral contraceptives). We offered an implant   and formed two study groups: implant and short-acting. For contraceptive discontinuation/pregnancy, we used log-rank tests and proportional hazards models. We applied intent-to-treat principles to evaluate the role of initial method choice on future pregnancy.

Results

Twenty-four percent opted for an implant (n=97) and the remainder for a short-acting method (n=299) The 18-month discontinuation probability was 21 per 100 for implant users and 43 per 100 for the short-acting method group (p = 0.001). Twenty-two unintended pregnancies occurred; all were among the short-acting group. The adjusted relative risk of pregnancy among the short-acting group vs. implant group was 7.4 (95% CI: 1.6, 34.5).

Conclusions

Many young Kenyan women found implants to be a reasonable alternative to short-acting methods. Having choice is essential and starting on implants provides substantial and clear protection from unintended pregnancy, relative to short-acting methods.

1. Introduction

Unintended pregnancy continues to be a well-documented and common problem worldwide [1]. In periodic international surveys conducted over the past 30 years [2], reproductive-aged women have candidly shared personal information about their last pregnancies. In sub-Saharan Africa, 40% of pregnancies are unintended [3]; thus, over the last decade alone, approximately 170 million unintended pregnancies have occurred in the region. Lifetime risks of mortality from pregnancy in sub-Saharan Africa are one in 16 [4]. The dangers are particularly acute for women under 25 years of age in sub-Saharan Africa; that population accounts for 55% of unsafe abortions in the region. In contrast, the burden is less on that age group in developing nations of Asia (30%) and Latin America/Caribbean (42%) [5].

Even among women with good access to contraception, unintended pregnancy is common. In the US, for example, approximately 48% of unintended pregnancies occur in the same month that contraception is used [6] because some methods are prone to higher failure rates in actual use [7]. Similar problems occur in the UK [8]. Reliance on less effective methods is often an artifact of health systems and factors completely outside the control of potential users, particularly in resource-poor settings [9]. In sub-Saharan Africa, contraceptive use is low and dominated by the least effective methods [10]. Non-use and use of ineffective methods of contraception contribute to the global burden of disease and mortality [11]. Unfettered access to all forms of contraception will help alleviate the problem of unintended pregnancy and death.

Subdermal contraceptive implants and intrauterine devices (IUDs) are long-acting products that have important advantages over other forms of reversible contraception. Long-acting methods are in the top tier of contraceptive effectiveness, in part, because they do not require frequent re-dosing that often leads to lapses in protection. Short-acting methods such as injectables and pills are popular in many African countries, but consistent use is under constant threat from commodity stock-outs at clinics, difficulty of returning to a clinic for services, ambivalence toward pregnancy/contraception, onset of side effects, and other factors. Voluntary use of an implant instead of contraceptive pills or injectables may help prevent unintended pregnancy in sub-Saharan Africa [12]. As implants become more affordable for international donor agencies [13], the opportunities for expanded use are now feasible. Improving availability of all long-acting methods will enable longer-term users to shift off short-acting methods and thus alleviate stock-out problems for those products.

Though long-acting methods are commonly described as the most effective forms of contraception, this characterization is potentially biased due to underlying, immeasurable, and differential motivations that exist to avoid pregnancy and the role these factors may have on method selection. For example, on average, older women might have higher motivations to avoid pregnancy and therefore select the most effective methods. Widely-accepted effectiveness measures do not take this information into account and are based on cross-sectional surveys of respondents who cite method failure retrospectively [14]. Comparative effectiveness research is lacking in the field of contraception [15].

Among young women in sub-Saharan Africa, use of long-acting methods is scant, yet rates of unintended pregnancy are high. We conducted this study to 1) measure uptake of implants in a young African population and 2) assess the technology's potential to prevent unintended pregnancy relative to the alternatives. Will many young women in this setting have an implant removed and experience pregnancy at similar levels to a comparison group? Will the decision to try an implant, instead of the alternatives, demonstrate convincing evidence of higher effectiveness, independent of other factors? Thus, the key aims of the study were to isolate, measure, and compare how initial method choice leads to discontinuation and pregnancy.

2. Methods and methods

We conducted this prospective cohort study at Lang'ata Health Centre in Nairobi, Kenya. Recruitment began in November 2008 and was completed in June 2009. The follow-up period lasted for 18 months for each participant, ending in February 2011. The protocol for this study was reviewed and approved by the Protection of Human Subjects Committee (Durham, NC, USA) and the Kenya Medical Research Institute (Nairobi, Kenya); women enrolled voluntarily after the written informed consent process.

All women who sought family planning services and agreed to be interviewed were screened for eligibility. We applied four key inclusion criteria: 18-24 years old, desire for combined oral contraceptives (COC) or the injectable depot medroxyprogesterone acetate (DMPA), possession of a working cell phone, and willingness to be contacted via cell phone. We excluded women who reported a pregnancy in the last six months (to avoid possible sub-fecund intervals) or had *a* *priori* desire for a subdermal implant. We excluded the latter group to eliminate selection bias and to focus the research on a population that might be considered for any future counseling/programmatic intervention.

Participants could choose the method they originally sought or opt for a subdermal implant (a two-rod levonorgestrel product, which was donated by the funding agency). The implant used in our study provides up to five years of contraceptive protection; in contrast, DMPA injections are needed every 3-4 months. We provided all methods free of charge and we told all participants they could stop using any method at any time for any reason. In addition, participants who wanted to switch methods were permitted to do so. Other details on enrollment are described elsewhere [16].

We did not require clinic visits or provide an incentive to return; this would have created an artificial reason to seek services, possibly leading to biased estimates of method continuation rates. To maintain contact with participants, we credited their cell phone accounts via periodic electronic transfers. In total, each participant was eligible for 60 min of air time (about $7 in value). We conducted follow-up interviews at 1, 6, 12, and 18 months after enrollment and asked participants about their current use of a method, incidence of side effects, and any pregnancies.

Based on initial contraceptive choices made by participants, we formed two groups: implant users and short-acting hormonal method users (DMPA and COC). The primary study outcome was pregnancy. If a participant reported pregnancy, we asked if it was wanted at that time, later, or not at all; the latter two categories defined unintended pregnancy. The secondary outcome was contraceptive discontinuation: removal of an implant or discontinuing short-acting contraception. We defined two types of discontinuation events: (1) any change from initial (specific) method and (2) any change off short-acting hormonal methods (as a combined category) or the implant. In this latter definition, switching between oral contraceptives and an injectable contraceptive was considered continued protection using short-acting methods.

The study size of approximately 400 participants was based on the assumptions that half would choose the implant and 25% of short-acting users would become pregnant over the 18-month period. We stipulated a two-sided test at the 0.05 significance level to detect a possible 50% reduction in the cumulative probability of pregnancy among the implant users.

We used intent-to-treat principles in the analysis to enable direct comparison of taking different paths to prevent unintended pregnancy. Kaplan-Meier methods were used for estimating the 12- and 18-month cumulative probabilities of method discontinuation and unintended pregnancy. For time to event analyses, first episode was used and subsequent follow-up data were censored. Last follow-up form and calculated time for contraceptive protection (if no interruptions occurred) were used for participants who did not experience the event of interest. To compare statistically the two cohorts on these outcomes, we used log-rank tests and Cox proportional hazard models to estimate the relative risk of DMPA/COC group vs. implant group adjusting for potential confounders. For DMPA users, we used a strict cut-off of 90 days for the re-injection window; however, we also performed sensitivity analyses using a 120-day window. For oral contraceptive users, date of taking the last dose was used for calculating time to discontinuation.

Because initial method choice is often related to other factors that are directly associated with the study outcomes, we assessed potential confounding in several ways. First, we used previously identified factors associated with preferences for a particular contraceptive method [16]; these included health concerns and inconveniences of using short-acting methods. Second, we used standard sociodemographic characteristics and baseline plans for future pregnancy.

The data were double-entered using open source software EpiInfo version 6.04 and SAS® version 9.2 was used for the analysis. We followed the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for reporting our results [17].

3. Results

We approached 774 consecutive family planning clients and 348 (45%) were ineligible to participate (Fig. 1). The main reasons for ineligibility were incorrect age (157), lack of a cell phone (122), pregnant in the last six months (90), and not willing to accept phone calls (44); many ineligible women cited multiple reasons. Of the 426 eligible clients, a total of 399 women enrolled voluntarily and 27 (6.3%) did not want to participate. Three participants who enrolled were later found to be ineligible and their participation was terminated. Four percent of the study population was completely lost to follow-up.

The final prospective cohort consisted of 396 participants; 97 (24%) chose the implant and 299 (76%) opted for short-acting hormonal methods. In the latter group, 39 chose combined oral contraceptives and 260 chose DMPA. The two study groups were similar on most sociodemographic characteristics (Table 1). However, implant users were better educated and wanted lengthier method use compared to short-acting users (p value <0.05). In addition, compared to short-acting users, a higher percentage of implant users felt that the body needs a break from short-acting hormonal methods and that it is difficult to return to a clinic.

Over the course of 18 months, the short-acting hormonal group was more likely to stop using that category of contraception compared to implant users (Fig. 2). Using Kaplan-Meier techniques and log-rank tests, the probability of discontinuation at 12 months was 36 per 100 person-years for short-acting users compared to 18 per 100 for the implant users (p value = 0.002). The 18-month estimates were 43 and 21 per 100 person-years, respectively (p value = 0.001).

The two cohorts experienced other profound differences in patterns of contraceptive use, reasons for discontinuation, and incidence of pregnancy (Table 2). In the 18-month observation period, 65% of short-acting users stopped using their specific initial method; this compared to only 19% of implant users. Nearly half of short-acting users stopped because of various challenges related to re-dosing requirements. DMPA-specific discontinuation rates were three times higher than implant rates at 12 and 18 months. The percent of women switching to the other group during follow-up was similar (about 8%).

Pregnancies were disproportionately high among the short-acting method users. Short-acting hormonal users experienced 33 total pregnancies and 22 unintended pregnancies; no implant user became pregnant unless it was planned. (This unanticipated result of zero unintended pregnancies in the implant group created statistical limitations that prohibited estimating a relative risk.) The probability of unintended pregnancy during 18 months of follow-up was 8.5 per 100 person-years among women in the short-acting study group.

Even after controlling for key covariates, the risk of method-specific discontinuation was about five times higher for DMPA and COC users (separately) compared to implant users (Table 3). As a combined category, DMPA/COC users were over twice as likely to discontinue their initial contraceptive strategy relative to implant users. In a separate sensitivity analysis, we recalculated hazard ratios using up to 120 days of protection for each injection of DMPA; the ratios were very similar (data not shown). Among a subset of participants who wanted at least two years of pregnancy protection at the time of enrollment, DMPA/COC users were seven times more likely to become pregnant (unintended or intended) within 18 months compared to implant users. (For this last analysis, it was necessary to combine unintended and intended pregnancies for modeling requirements.)

4. Discussion

In this prospective cohort study, we found that contraceptive implants were a well-accepted option in a young Kenyan population that was initially seeking a short-acting method; uptake was favorable and the continuation rate was high. After adjusting for many factors, the decision to try an implant conferred independent protection from pregnancy relative to the alternative short-acting options, even in a relatively short time frame. Put another way, starting out with a short-acting method led to a 7-fold increase in pregnancy, relative to the implant. Increasing opportunities to try this important class of contraceptive technology may deliver personal and societal benefits, particularly for young women who may desire higher education and/or employment. The pregnancy-protection demonstrated in this study in Kenya was similar to ground-breaking research conducted 20 years ago in the US among adolescents using the first subdermal implant [18, 19]. Another key finding in Kenya was the high continuation rate with the implant (80% at 18 months); this rate in a young, high-fertility population is similar to internationally-accepted estimates on the same product involving primarily older women [20-22]. However even though 80% retained use of the implant, we cannot assume that all users were completely satisfied with the method. Perhaps we can only say that voluntary continued use appeared to be more desirable than the alternatives; this may reflect conscious decisions to remain protected from pregnancy or simply inertia (easier to keep using the product). In other countries, high continuation rates of long-acting reversible contraception make these methods more cost-effective than the alternatives [23-25].

The primary limitation of our study traces back to design; we did not conduct a randomized trial on this topic because of programmatic concerns. Thus, in the analysis, we had to rely on standard epidemiologic tools to control for confounding. In terms of method discontinuation, arguably, the cohort of women who chose a short-acting method may have simply exercised their shorter-term needs and stopped using contraception earlier than implant users (who had longer-term needs). Certainly, this "confounding by indication" may explain some behavior, however only 4% of short-acting users stopped using their method to become pregnant. The short-acting group was composed of DMPA users (87%) and COC users (13%). It is difficult to know for sure whether discontinuation rates and unintended pregnancy would have been higher with a greater proportion of COC use. Finally, the implants donated and used in this study were earmarked for this activity; regular Kenyan government procurement and provision of implants may not be able to achieve this impact on a national scale.

We experienced statistical limitations because all of the unintended pregnancies occurred in the DMPA/COC group; with zero unintended pregnancies in the implant cohort, some analyses were mathematically impossible to pursue. Nevertheless, it was feasible to model all pregnancies among a subset of participants that initially wanted two years of contraceptive protection; this allowed us to address our primary study objective. Though 96% of participants contributed some follow-up information, 86% and 82% contributed updates at 12+ and 18+ months, respectively. We were hoping to have over 90% rates given the eligibility criterion of having a cell phone. Higher follow-up rates might have been achievable with incentives to return to the clinic; however, this would have created an artificial environment and biased our secondary outcome (continuation rates measured in a typical setting).

The prospective data collection and natural research environment are important strengths. Together, these strengths generated tangible outcomes for illustrating the incidence and consequences of method discontinuation. The results show just how difficult it can be to avoid disruptions in contraceptive use and unintended pregnancy. This study was conducted in a large urban metropolis; young Kenyan women in rural areas probably face higher hurdles to continue using short-acting contraceptives. Young women in other countries in sub-Saharan Africa experience similar situations.

International donor agencies have steadily increased implant procurement for sub-Saharan Africa over the past four years, from 406,000 units in 2007 to over 1.6 million units in 2010 [26]. However, approximately 30 million women in sub-Saharan Africa have an unmet need for contraception [27]. Among those who are currently using short-acting hormonal methods (approximately 18 million), many might choose an implant if the opportunity were available. Given the challenges of providing safe sterilization services, implants and IUDs are also important long-acting alternatives for women who do not want more children. Maternal deaths and morbidity, HIV transmission, and orphanage [28] are avoidable outcomes with improved access to all type of contraceptive methods. New efforts are needed to ensure that implants and other long-acting methods are readily available to all women seeking reversible contraception, regardless of age or other inappropriate barriers.

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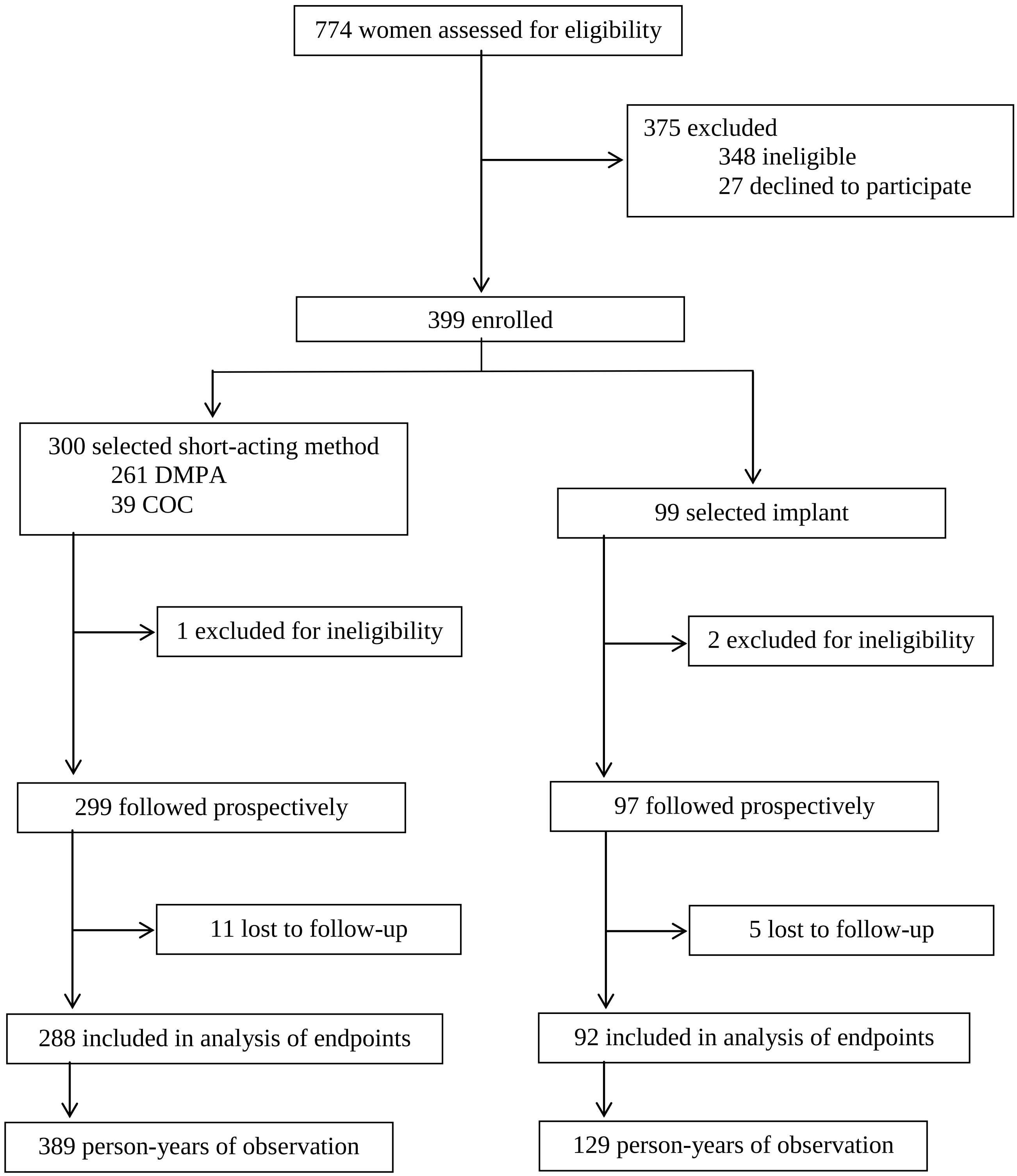

Fig. 1. Profile of observational cohort.

Table 1
Characteristics of short-acting hormonal method users and subdermal implant users

Characteristic	**Short-acting methods (n=299)* %**	**Subdermal implant (n=97) %**
Age, years		
18-19	11.4	11.3
20-22	39.8	46.4
23-24	48.8	42.3
Education †		
Less than primary	20.7	20.6
Completed primary	60.2	47.4
Some secondary or higher	19.1	32.0
Two or more children	39.5	42.3
Married	86.0	83.5
Length of time in current relationship		
<1 year	16.0	20.6
1-3 years	46.5	37.1
3+ years	37.5	42.3
Wants another child	92.3	88.7
Ideal timing of next pregnancy †		
Within 2 years or unsure	30.4	13.4
25-48 months	22.7	21.6
>4 years or never	46.8	65·0
Had a previous unintended pregnancy	57.2	65.0
Would continue using method even if it caused menstrual changes	80.6	80.4
Believes that the body needs an occasional break from DMPA or COCs †	49.2	70.1
Difficult to return to clinic for resupply of method †	47.5	65.0
Believes long-term use of DMPA/COC impairs future fertility	34.8	41.2

* includes 260 users of DMPA and 39 users of COC.
† p value <0.05, chi-square test.

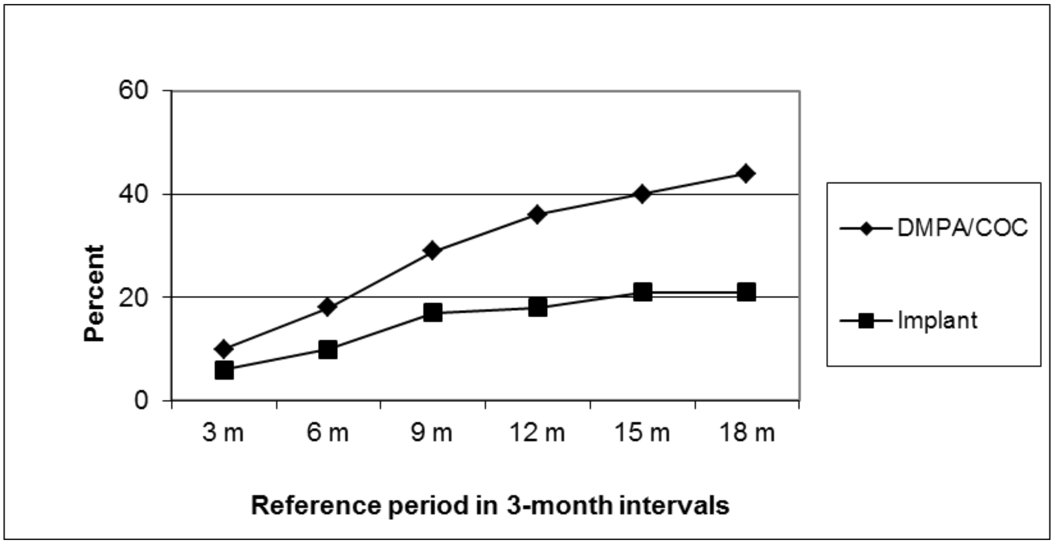

Fig. 2. Cumulative probability of discontinuation by method and period.

Table 2
Method discontinuation and unintended pregnancy in 18-month period

Outcome	**Initial group**	
	Short-acting methods (n=299)	**Subdermal implant (n=97)**
Discontinuation		
Number (%) who stopped using initial (specific) method	195 (65.2)	18 (18.6)
Reason for stopping use of initial method (percent distribution)		
To become pregnant	4.1	16.7
Unexpected pregnancy	3.1	0
Side effects	24.6	61.1
Abstinence	9.7	0
Cost, stock-outs, inconvenience	46.2	0
Other	10.8	22.2
Number (%) who discontinued initial group during follow-up period*	115 (38.5)	18 (18.6)
Method-specific discontinuation probabilities		
12-month	DMPA: 57.7	18.2
18-month	DMPA: 66.2	20.6
Number (%) of cross-overs during follow-up period†	23 (7.7)	8 (8.2)
Pregnancies		
Total number of pregnancies	33	3
Number of unintended pregnancies	22 ‡	0
18-month unintended pregnancy probability	8.5	0.0
Maximum person-years of follow-up	389	129

* Discontinuation curves in Fig. 2 are based on this measure.
† Switching from short-acting to an implant or vice versa.
‡ 21 unintended pregnancies among the 260 initial DMPA users and 1 among the initial 39 COC users.

Table 3
Risk of outcome if selecting DMPA/COC as initial contraceptive choice, relative to implant selection

Outcome of interest	Hazard ratio (95% CI) Unadjusted	Hazard ratio (95% CI) Adjusted
Discontinuing initial (specific) method*		
DMPA	4.4 (2.2, 8.6)	4.9 (2.4, 9.7)
COC	5.5 (3.4, 8.9)	6·1 (3.7, 10.2)
Implant	ref	ref
Discontinuing initial study group †		
DMPA/COC	2.3 (1.4, 3.9)	2.4 (1.4, 4.0)
Implant	ref	ref
Pregnancy ‡		
DMPA/COC	5.4 (1.3, 23.6)	7.4 (1.6, 34.5)
Implant	ref	ref

Note: Adjusted estimates control for education, ideal timing of next pregnancy (1, 2, 3, and 4+ years), ease of returning to clinic for resupply, opinions on health effects of short-acting hormonal methods.
* Discontinuing use of DMPA, COC, and implants separately.
† Discontinuing DMPA/COC and implants as study groups.
‡ Among participants who wanted at least 2 years of pregnancy protection, yet became pregnant within 18 months. Due to zero unintended pregnancies in the implant group, it was not feasible to estimate a hazard ratio for unintended pregnancy.

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