HHS Public Access

Author manuscript

Contraception. Author manuscript; available in PMC 2024 July 24.

Published in final edited form as:

Contraception. 2015 December ; 92(6): 560–566. doi:10.1016/j.contraception.2015.06.009.

Effects of initiating a contraceptive implant on subsequent condom use: A randomized controlled trial☆,,☆☆

Carole Rattray[a], **Jeffrey Wiener**[b], **Jennifer Legardy-Williams**[b], **Elizabeth Costenbader**[c], **Karen Pazol**[b], **Natalie Medley-Singh**[a], **Margaret C. Snead**[a], **Markus J. Steiner**[c], **Denise J. Jamieson**[b], **Lee Warner**[b], **Maria F. Gallo**[d], **Tina Hylton-Kong**[e], **Athena P. Kourtis**[b,*]

[a]University Hospital of the West Indies, Kingston, Jamaica

[b]Centers for Disease Control and Prevention, Atlanta, GA, USA

[c]Family Health International (FHI 360), Research Triangle Park, NC, USA

[d]Division of Epidemiology, The Ohio State University College of Public Health, Columbus, OH, USA

[e]Epidemiology Research and Training Unit, Ministry of Health, Kingston, Jamaica

Abstract

Objective: To evaluate whether initiation of a contraceptive implant, a method of long-acting reversible contraception, reduces condom use, as measured by a biomarker of recent semen exposure [prostate-specific antigen (PSA)].

Study design: We conducted a randomized controlled clinical trial in which 414 Jamaican women at high risk for sexually transmitted infections (STIs) attending family planning clinics received the contraceptive implant at baseline ("immediate" insertion arm, *N*= 208) or at the end ("delayed" insertion arm, *N*= 206) of a 3-month study period. Participants were tested for PSA at baseline and two follow-up study visits and were asked about their sexual activity and condom use.

Results: At baseline, 24.9% of women tested positive for PSA. At both follow-up visits, the prevalence of PSA detection did not significantly differ between the immediate versus delayed insertion arm [1-month: 26.1% vs. 20.2%, prevalence ratio (PR)=1.3, 95% confidence interval (CI)=0.9–1.9; 3-month: 25.6% vs. 23.1%, PR= 1.1, 95% CI=0.8–1.6]. The change in PSA positivity over the three study visits was not significantly larger in the immediate arm compared to the delayed arm (1-sided p-value of .15).

Conclusions: Contraceptive implants can be successfully introduced into a population at high risk of unintended pregnancy and STIs without a biologically detectable difference in unprotected sex in the short term. This information strengthens the evidence to support promotion of implants

---

☆CDC Disclaimer: The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

☆☆Clinical Trial Registration: ClinicalTrials.gov, www.clinicaltrials.gov, (NCT01684358).

*Corresponding author. Division of Reproductive Health, Women's Health and Fertility Branch, Centers for Disease Control and Prevention, 4770 Buford Highway, MS- F-74, Atlanta, GA 30341, USA. apk3@cdc.gov (A.P. Kourtis).

in such populations and can help refine counseling for promoting and maintaining use of condoms among women who choose to use implants.

Implications: Sex unprotected by a condom was not higher over 3 months in women receiving a contraceptive implant, compared with those not receiving the implant.

Keywords

Contraceptive implant; Randomized controlled trial; LARC; Condom use; PSA

1. Introduction

Unintended pregnancy continues to be an important public health issue worldwide. An estimated 213 million pregnancies occurred in 2012 worldwide and approximately 40% of those were unintended [1]. For Latin American and Caribbean populations, unplanned pregnancies represented 45% of all pregnancies in 2012 [1]. Unplanned pregnancies result from lack of contraceptive access, nonuse, incorrect or inconsistent use of contraceptives or contraceptive failure and have adverse health outcomes for women and infants, as well as financial, and social consequences for women and their families, countries and societies [2–6].

Increasing use of long-acting reversible contraception (LARC) methods, such as subdermal contraceptive implants, by women of reproductive ages has been advocated as a strategy to reduce unintended pregnancy [7–12]. Of note, contraceptive implants have been shown to be highly effective, safe and cost effective and to require little user maintenance [8,10,13–15]. Implants, however, offer no protection against sexually transmitted infections (STIs), including HIV. Because of the high degree of effectiveness of implants against pregnancy, there is concern that women initiating such methods or their partners may be less motivated to use condoms, thus placing both partners at increased risk for HIV/STI [16,17]. Most available evidence suggests that LARC is associated with a greater reduction in condom use than other less effective methods such as oral contraceptives and injectables [18–22], although this finding has not been consistently demonstrated [23,24]. However, all of these studies have been limited by a lack of randomized design, small sample sizes or reliance on self-reports of condom use with unknown validity. Given these limitations, we conducted a randomized clinical trial with a delayed intervention control group to assess whether initiation of a contraceptive implant would lead to less condom use as measured with prostate-specific antigen (PSA), a vaginal biomarker of recent semen exposure [25–28].

2. Material and methods

2.1. Study population

Study participants were referred and recruited from seven maternal and child health and family planning public clinics in Kingston, Jamaica, and through peer-to-peer referrals. Recruitment took place from September 2012 to October 2013 with follow-up visits continuing until January 2014. Women were eligible for enrollment if they were willing to be randomized to receive Sino-implant (II) immediately or after a 3-month delay, were 18–44 years of age, were not currently using or planning to use another LARC method

in the next 3 months, had not had a hysterectomy or planned to have one in the next 3 months, were deemed to be a good candidate for enrollment by the study clinicians and had no contraindications to hormonal implant use per the World Health Organization's guidance [13]. Contraindications consisted of lactating and within first 3 weeks postpartum, acute deep venous thrombosis or pulmonary embolism, systemic lupus erythematosus, migraine with aura, unexplained vaginal bleeding and current or past history of ischemic heart disease. Finally, women known to be HIV infected based on self-report or a previous positive test were excluded from this study, because this population could have differed with respect to motivations to use condoms and they tended to receive more intensive safer-sex counseling than other women.

Women who provided written informed consent for enrollment received a urine test to screen for pregnancy. Women who had a positive urine pregnancy test were discontinued from the study and were referred to prenatal services.

2.2. Study product

Sino-implant (II) is a two-rod contraceptive implant containing 75 mg levonorgestrel in each rod. It is manufactured in China, by the Shanghai Dahua Pharmaceutical Company, and marketed in more than 20 countries under the names of Zarin, Trust, Simplant or Femplant [29]. Once inserted, the implant is effective for up to 4 years. Prior to study initiation, the Jamaican Ministry of Health approved (on April 27, 2012) the registration of the Sino-implant (II) for distribution and use in the country.

2.3. Study design

Using permuted block randomization performed by a pseudorandom number generator and a system of sequentially numbered, sealed envelopes, women were randomly assigned to one of two study arms: (1) "immediate" insertion at baseline or (2) "delayed" insertion after 3 months of follow-up. Participants and local staff were not blinded to intervention arm assignment; however, laboratory staff remained blinded throughout the study.

At baseline, study nurses orally administered questionnaires to collect information on participant demographics, sexual activity and condom use. Study clinicians provided safer-sex and contraceptive counseling, conducted clinical assessments and physical (including pelvic) examinations and collected vaginal swabs. After 39 weeks of enrollment and follow-up, the Pregnancy Exclusion Checklist [30] was incorporated into the contraceptive counseling session as an additional way to screen out very early pregnancies undetectable with a urine pregnancy test. The randomization envelope was opened after safer-sex counseling was provided in order to ensure that participants in both study arms received the same condom counseling messages. Vaginal swabs were tested for PSA, which is a biomarker of semen detectable for up to 48 h postexposure [25–28,31]. Study clinicians inserted the Sino-implant (II) into participants who were randomized to the immediate insertion arm and provided male condoms. In addition, women randomized to the delayed insertion arm were provided male condoms and, if desired, oral contraceptives for the 3-month follow-up period.

Women were scheduled to return to the clinic for follow-up at 1 and 3 months after enrollment. At both follow-up visits, study staff again administered a questionnaire, conducted safer-sex and contraceptive counseling, conducted clinical assessments and physical (including pelvic) examinations, collected vaginal swabs and distributed male condoms. Women in the immediate insertion arm were administered a questionnaire to assess implant acceptability. Urine pregnancy testing was conducted at each of the follow-up visits for women who reported symptoms compatible with pregnancy and at the 3-month follow-up visit for women who were randomized to the delayed insertion arm and remained interested in receiving the implant at that point in time. At the 3-month visit, all participants were administered a questionnaire on condom acceptability.

The study protocol was approved by the Jamaican Ministry of Health, the US Centers for Disease Control and Prevention (CDC) and Faculty of Medical Sciences at University of West Indies ethical review boards and was registered with ClinicalTrials.gov (NCT01684358). CONSORT guidelines for reporting on randomized controlled trials were followed [32].

2.4. Laboratory testing for PSA

PSA testing was conducted onsite using published procedures for ABAcard 30 (Abacus Diagnostics, West Hills, CA), a rapid, semiquantitative test kit [33]. In short, vaginal swab eluate was added to the sample well of the test card and, at 10 min, the results were recorded. Samples were considered negative for PSA if there was a visible line in the control area of the test cards and not the test area. Samples were considered low or high positive for PSA based on the intensity of visible, pink test line in the test and control areas compared with PSA standards. High and low positives were consistent with standard solutions containing 23 ng/ml PSA or greater and 4 to less than 23 ng/ml PSA, respectively. Quality assurance testing was conducted on 350 swabs or remnant eluents from 125 participants using a quantitative total PSA assay (Abbott Diagnostics, Abbott Park, IL) at the CDC. Using the quantitative test as the reference standard and including “low positives” in the positive category, we found 84% sensitivity and 81% specificity for the ABAcard results. PSA detection can be negatively affected when specimens are not tested soon after collection [34]. Given that the specimens were stored frozen over 6–13 months prior to testing with the Abbott assay, PSA loss could have occurred in some specimens, which could account for the observed specificity.

2.5. Statistical analyses

We estimated that 8% of women would test positive for PSA at enrollment based on a previous trial at the same study site [35]. Using this estimate and the method described by Jung et al. [36], we determined that a total sample size of 414 participants would be necessary to detect an increase in PSA positivity to 16% at the 3-month follow-up visit in the immediate insertion arm with a 7.5% lost to follow-up rate. This calculation involved fitting a repeated-measurements model using generalized estimating equations (GEE) and assessing the increase in the immediate insertion arm over time using a 1-tailed test with α=0.05 and 80% power.

An intent-to-treat analysis was used to compare the PSA positivity outcome between the two study arms. To assess the change in PSA positivity over time between the two study arms, repeated-measurements models were fit using GEE and the interaction between study arm and follow-up time was evaluated using a Wald test. The prevalence of PSA positivity and of self-reported unprotected sex was compared between arms at each follow-up visit using prevalence ratios (PRs) with 95% confidence intervals (CIs). Concordance between PSA and self-reported unprotected sex was assessed using Cohen's Kappa coefficient. All analyses were conducted using SAS (SAS Institute, version 9.3, Cary, NC).

3. Results

Of the 555 women who were recruited or referred to the study for screening, 89 (16%) did not meet the initial screening eligibility criteria. Of the remaining 466 women, 2 (0.4%) had positive urine pregnancy tests, 42 (9%) completed their initial screening over the phone but did not attend the clinic to complete the screening process and 8 (2%) declined enrollment consent (Fig. 1). Therefore, 414 women were enrolled and randomized in the study: 208 in the "immediate" and 206 in the "delayed" arm. Of these, 389 (94%) women completed both follow-up visits. (Twelve were lost to follow-up before the 1-month visit, 12 were lost to follow-up between the 1-month and 3-month visits and 1 discontinued for personal reasons before the 1-month visit.)

Most baseline characteristics for the two groups were similar (Table 1). Participants in both arms had a median age of 25 years and a median of 2 live births. Most women had completed high school, never exchanged gifts or money for sex and had less than 4 alcoholic drinks in 1 day in the past week. Only 2% had ever used a contraceptive implant. In the month prior to enrollment, the method of contraception most commonly reported was male condoms (58%, immediate insertion vs. 52%, delayed insertion) followed by no method of contraception (26%, immediate insertion vs. 23%, delayed insertion). While depot medroxyprogesterone acetate (DMPA) use in the past month was similar between the immediate insertion and delayed insertion arms (9% vs. 8%, respectively), use of oral contraceptive pills in the past month was lower in the immediate insertion (13%) than in the delayed insertion arm (21%). Additionally, 66% of women in the immediate arm were single and never married compared to 75% in the "delayed" arm.

At baseline, PSA positivity was 23% in the immediate insertion arm and 27% in the delayed insertion arm (Table 1). Self-reported unprotected sex at baseline was 17% in the immediate insertion arm and 14% in the delayed insertion arm when reported for the past 2 days and was 23% in both arms when reported for the past week.

The proportion of women with PSA detected was 26% at both the 1-month and the 3-month study visits in the immediate insertion arm, as compared with 20% at 1 month and 23% at 3 months in the delayed insertion arm (Table 2). This difference between study arms was not statistically significant at either study visit. The increase in PSA detection over all three study visits was also not significantly larger in the immediate insertion arm than in the delayed insertion arm when compared using a repeated-measurements model (1-sided p-value of .15).

3.1. Self-reported unprotected sex

The frequency of self-reported unprotected sex was higher in the immediate insertion arm compared to the delayed insertion arm at both follow-up visits when reported for the past 2 days (1-month PR=1.8, 95% CI 1.1–2.8; 3-month PR=1.5, 95% CI 0.9–2.5) and when reported for the past week (1-month PR=1.5, 95% CI 1.1–2.1; 3-month PR=1.5, 95% CI 1.0–2.2).

The concordance between PSA detection and self-reported unprotected sex was fair for both unprotected sex in the past 2 days (Kappa coefficient=0.4, 95% CI 0.3–0.4) and in the past week (Kappa coefficient=0.4, 95% CI 0.3–0.4). A substantial proportion of those testing positive for PSA reported no unprotected sex in the past week (53% at baseline, 44% at 1 month, 49% at 3 months).

4. Discussion

Given the high rate of effectiveness of contraceptive implants against pregnancy, there are concerns that women initiating implants may be less motivated to use condoms or may not be able to persuade their partners to use condoms solely for STI prevention. This concern is supported by previous research, which has found that LARCs are associated with reduced condom use [18–24,37,38], and that this reduction in condom use is greater with LARCs compared to other, less effective contraceptive methods [18–22]. However, all previous research has been based on nonrandomized observational studies that used self-reported data for their measure of condom use. In contrast, in the present randomized trial using PSA as an objective biomarker of semen exposure, we did not find evidence of reduced condom use after insertion of a progestin implant. The PR of testing positive for PSA was not significantly higher for women who had received the contraceptive implant as compared to women who had not, and the change in PSA detection over all three study visits did not differ significantly between the study arms.

Use of a nonrandomized design can introduce bias in that women who choose implants may differ in important ways from women who choose other methods — in particular, women who perceive themselves to be at low risk for HIV and other STIs may be more likely to use implants and may have inherently different condom use patterns [39]. Our study is the first, to our knowledge, to address this question using a randomized design and a delayed intervention control group with an objective marker of semen exposure. The delayed intervention study design includes a control group who is equally motivated to use the implant and it reduces the reluctance of participants to enroll in a study with no apparent benefit to the control group.

The percentage of women in the immediate implant insertion arm who reported having unprotected sex in the past week was greater than in the delayed arm, with the largest frequency of unprotected sex reported at 1 month following implant insertion. However, the correlation of the two measures was fair (Kappa coefficient=0.4). The lack of a stronger correlation points to previously recognized limitations of self-report of sensitive behaviors. Use of self-reported data for condom use may be inaccurate for many reasons, including social desirability or recall bias [40–43]. Evidence on the underreporting of unprotected

sex is provided by studies that have detected biological markers of semen in vaginal fluid specimens collected from women who denied recent exposure. The use of an objective marker of semen exposure in the current study circumvents the problems of relying only on self-report.

Based on prior research from the same study site [35], it was estimated that approximately 8% of samples at baseline would test positive for PSA. Accordingly, this study was powered to detect a doubling of this PSA positivity rate (i.e., a doubling of the rate of sex without a condom). This large decrease in condom use after implant insertion did not occur. However, given the higher percentage of women in this study testing positive for PSA at baseline (i.e., engaging in sex without a condom or despite condom use), future research is needed that is powered to detect smaller changes in condom use in conjunction with the insertion of a contraceptive implant. Using the observed baseline PSA positivity rate of 24.9%, this study had 80% power to detect an increase to at least 35.6% testing positive for PSA at the 3-month follow-up visit in the immediate insertion arm (a much larger increase than observed in this study). The high rates of PSA positivity at baseline in our study participants also indicate a population at high risk for unintended pregnancy and STI who would benefit the most from LARC and condom promotion strategies.

Prior studies have found that self-reported use of condoms with LARCs is more common among women with multiple partners as compared to women who are in monogamous relationships [18,21]. The higher percentage of married or cohabiting women in the immediate insertion as compared to the delayed insertion arm may have contributed to the greater increase in self-reported sex without a condom. Additionally, given that this was an unblinded trial to participants, women in the delayed arm may have been more compelled to provide socially desirable responses at visits prior to implant insertion, particularly for pregnancy prevention, which could account for lower rates of self-reported unprotected sex at the 1-month and 3-month follow-up visits in this arm.

A limitation of this study is that condom use was evaluated for only 3 months, rather than a more extended period following the insertion of an implant. Prior research has shown that self-reported condom use only decreases over time with the use of more effective methods and remains high at 3 months [44–46]. This study also found a larger lost to follow-up rate in the delayed insertion arm (9.7%) compared to the immediate insertion arm (2.4%) likely related to the delayed intervention study design, which could be a potential source of bias in the study results. Another limitation is the use of PSA as a proxy for condom use during the whole study period. It is known that the concentration of PSA collected from vaginal swabs is highest immediately following semen exposure and then decreases dramatically by 24 h before returning to background levels by 48 h [28,31]. Also, testing negative for PSA can be due to either condom use or no recent sex.

Future studies using a randomized design, along with longer follow-up and a biomarker of semen exposure, will be useful to more fully characterize possible declines in condom use with initiation and maintenance of implants. In addition, more studies are needed for determining the aspects of counseling that are most effective for promoting and maintaining the continued use of condoms when implants are used.

In conclusion, this study suggests that it is possible to introduce contraceptive implants into a population at high risk for unintended pregnancy and STI without a large decrease in the use of condoms, in the short term. These findings are particularly important in that our current study was the first to use a randomized study design and an objective biomarker of semen exposure to evaluate the influence of an implant on condom use.

Acknowledgements

The study is supported by the CDC, United States Agency for International Development, Family Health International (FHI 360) cooperative agreement, CA/GPO-A-00-05-00022.

The authors thank Sophon Bailey and Yanique Wallace for study coordination; Omar Mattis for recruitment and retention coordination; Drs. Raquel Gibson and Andrea Cattan for their assistance with patient care; nurses Carol Cooper Smith, Hazel Harris, Sandra Mills and Rachael Bryan for data collection and patient care; Leshawn Mendoza, Shashauna Eastman and James Partin for laboratory testing and support; Shemille Samuels for data entry; Lisa Flowers for data management; and Sarah Mullins for study monitoring.

References

[1]. Sedgh G, Singh S, Hussain R. Intended and unintended pregnancies worldwide in 2012 and recent trends. Stud Fam Plann 2014;45(3):301–14. [PubMed: 25207494]

[2]. Singh S, Sedgh G, Hussain R. Unintended pregnancy: worldwide levels, trends, and outcomes. Stud Fam Plann 2010;41(4):241–50. [PubMed: 21465725]

[3]. Dixit P, Ram F, Dwivedi LK. Determinants of unwanted pregnancies in India using matched case–control designs. BMC Pregnancy Childbirth 2012;12:84. [PubMed: 22883933]

[4]. Le HH, Connolly MP, Bahamondes L, Cecatti JG, Yu J, Hu HX. The burden of unintended pregnancies in Brazil: a social and public health system cost analysis. Int J Womens Health 2014;6:663–70. [PubMed: 25075201]

[5]. Kaufmann RB, Morris L, Spitz AM. Comparison of two question sequences for assessing pregnancy intentions. Am J Epidemiol 1997;145(9):810–6. [PubMed: 9143211]

[6]. Blumenthal PD, Voedisch A, Gemzell-Danielsson K. Strategies to prevent unintended pregnancy: increasing use of long-acting reversible contraception. Hum Reprod Update 2011;17(1):121–37. [PubMed: 20634208]

[7]. Finer LB, Jerman J, Kavanaugh ML. Changes in use of long-acting contraceptive methods in the United States, 2007–2009. Fertil Steril 2012;98(4):893–7. [PubMed: 22795639]

[8]. Trussell J, Henry N, Hassan F, Prezioso A, Law A, Filonenko A. Burden of unintended pregnancy in the United States: potential savings with increased use of long-acting reversible contraception. Contraception 2013;87(2):154–61. [PubMed: 22959904]

[9]. Speidel JJ, Harper CC, Shields WC. The potential of long-acting reversible contraception to decrease unintended pregnancy. Contraception 2008;78(3):197–200. [PubMed: 18692608]

[10]. Winner B, Peipert JF, Zhao Q, Buckel C, Madden T, Allsworth JE, et al. Effectiveness of long-acting reversible contraception. N Engl J Med 2012;366(21):1998–2007. [PubMed: 22621627]

[11]. Ott M, Sucato G. Committee on Adolescence. Contracept Adolesc 2014;29.

[12]. A.C.O.G. Committee. Opinion no. 450: increasing use of contraceptive implants and intrauterine devices to reduce unintended pregnancy. Obstet Gynecol 2009;114(6):1434–8. [PubMed: 20134301]

[13]. World Health Organization. Medical eligibility criteria for contraceptive use. World Health Organization; 2010.

[14]. Grimes DA. Forgettable contraception. Contraception 2009;80(6):497–9. [PubMed: 19913141]

[15]. Mavranezouli I, Wilkinson C. Long-acting reversible contraceptives: not only effective, but also a cost-effective option for the National Health Service. J Fam Plann Reprod Health Care 2006;32(1):3–5. [PubMed: 16492322]

[16]. Cates W, Steiner MJ. Dual protection against unintended pregnancy and sexually transmitted infections: what is the best contraceptive approach? Sex Transm Dis 2002;29(3):168–74. [PubMed: 11875378]

[17]. Glasier A Should healthcare professionals be advocating long-acting reversible contraception? Womens Health (Lond Engl) 2009;5(1):1–4. [PubMed: 19102633]

[18]. Pazol K, Kramer MR, Hogue CJ. Condoms for dual protection: patterns of use with highly effective contraceptive methods. Public Health Rep 2010;125(2):208–17. [PubMed: 20297747]

[19]. Santelli JS, Davis M, Celentano DD, Crump AD, Burwell LG. Combined use of condoms with other contraceptive methods among inner-city Baltimore women. Fam Plann Perspect 1995;27(2):74–8. [PubMed: 7796900]

[20]. Darney PD, Callegari LS, Swift A, Atkinson ES, Robert AM. Condom practices of urban teens using Norplant contraceptive implants, oral contraceptives, and condoms for contraception. Am J Obstet Gynecol 1999;180(4):929–37. [PubMed: 10203661]

[21]. Cushman LF, Romero D, Kalmuss D, Davidson AR, Heartwell S, Rulin M. Condom use among women choosing long-term hormonal contraception. Fam Plann Perspect 1998;30(5):240–3. [PubMed: 9782048]

[22]. Eisenberg DL, Allsworth JE, Zhao Q, Peipert JF. Correlates of dual-method contraceptive use: an analysis of the National Survey Of Family Growth (2006–2008). Infect Dis Obstet Gynecol 2012;2012:717163. [PubMed: 22505799]

[23]. Roye CF. Condom use by Hispanic and African-American adolescent girls who use hormonal contraception. J Adolesc Health 1998;23(4):205–11. [PubMed: 9763156]

[24]. Polaneczky M, Slap G, Forke C, Rappaport A, Sondheimer S. The use of levonorgestrel implants (Norplant) for contraception in adolescent mothers. N Engl J Med 1994;331(18):1201–6. [PubMed: 7935659]

[25]. Graves HC, Sensabaugh GF, Blake ET. Postcoital detection of a male-specific semen protein. Application to the investigation of rape. N Engl J Med 1985;312(6):338–43. [PubMed: 3881667]

[26]. Kamenev L, Leclercq M, Francois-Gerard C. An enzyme immunoassay for prostate-specific p30 antigen detection in the postcoital vaginal tract. J Forensic Sci Soc 1989;29(4):233–41. [PubMed: 2477492]

[27]. Lawson ML, Maculuso M, Bloom A, Hortin G, Hammond KR, Blackwell R. Objective markers of condom failure. Sex Transm Dis 1998;25(8):427–32. [PubMed: 9773437]

[28]. Macaluso M, Lawson L, Akers R, Valappil T, Hammond K, Blackwell R, et al. Prostate-specific antigen in vaginal fluid as a biologic marker of condom failure. Contraception 1999;59(3):195–201. [PubMed: 10382083]

[29]. Shanghai Dahua Pharmaceutical Company L. Sino-Implant (II) [package insert]; 1996 [Shanghai, China].

[30]. Tepper NK, Marchbanks PA, Curtis KM. Use of a checklist to rule out pregnancy: a systematic review. Contraception 2013;87(5):661–5. [PubMed: 23040127]

[31]. Jamshidi R, Penman-Aguilar A, Wiener J, Gallo MF, Zenilman JM, Melendez JH, et al. Detection of two biological markers of intercourse: prostate-specific antigen and Y-chromosomal DNA. Contraception 2013;88(6):749–57. [PubMed: 24028752]

[32]. Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMC Med 2010;8:18. [PubMed: 20334633]

[33]. Hobbs MM, Steiner MJ, Rich KD, Gallo MF, Alam A, Rahman M, et al. Good performance of rapid prostate-specific antigen test for detection of semen exposure in women: implications for qualitative research. Sex Transm Dis 2009;36(8):501–6. [PubMed: 19455082]

[34]. Gallo MF, Snead MC, Black CM, Brown TM, Kourtis AP, Jamieson DJ, et al. Optimal methods for collecting and storing vaginal specimens for prostate-specific antigen testing in research studies. Contraception 2013;87(6):830–5. [PubMed: 23121826]

[35]. Anderson C, Gallo MF, Hylton-Kong T, Steiner MJ, Hobbs MM, Macaluso M, et al. Randomized controlled trial on the effectiveness of counseling messages for avoiding unprotected sexual intercourse during sexually transmitted infection and reproductive tract infection treatment among female sexually transmitted infection clinic patients. Sex Transm Dis 2013;40(2):105–10. [PubMed: 23321990]

[36]. Jung SH, Ahn CW. Sample size for a two-group comparison of repeated binary measurements using GEE. Stat Med 2005;24(17):2583–96. [PubMed: 16118812]

[37]. Williams RL, Fortenberry JD. Dual use of long-acting reversible contraceptives and condoms among adolescents. J Adolesc Health 2013;52(4 Suppl):S29–34. [PubMed: 23535054]

[38]. Berenson AB, Wiemann CM. Use of levonorgestrel implants versus oral contraceptives in adolescence: a case–control study. Am J Obstet Gynecol 1995;172(4 Pt 1):1128–35. [PubMed: 7726249]

[39]. Gallo MF, Warner L, Jamieson DJ, Steiner MJ. Do women using long-acting reversible contraception reduce condom use? A novel study design incorporating semen biomarkers. Infect Dis Obstet Gynecol 2011;2011:107140. [PubMed: 21845022]

[40]. Stuart GS, Grimes DA. Social desirability bias in family planning studies: a neglected problem. Contraception 2009;80(2):108–12. [PubMed: 19631784]

[41]. Methodological Challenges in Biomedical HIV Prevention Trials. In: Lagakos S, & Gable A, editors. Washington, DC: National Academies Press; 2008.

[42]. Noar SM, Cole C, Carlyle K. Condom use measurement in 56 studies of sexual risk behavior: review and recommendations. Arch Sex Behav 2006;35(3):327–45. [PubMed: 16799837]

[43]. Catania JA, Gibson DR, Chitwood DD, Coates TJ. Methodological problems in AIDS behavioral research: influences on measurement error and participation bias in studies of sexual behavior. Psychol Bull 1990;108(3):339–62. [PubMed: 2270232]

[44]. Walsh JL, Fielder RL, Carey KB, Carey MP. Dual method use among a sample of first-year college women. Perspect Sex Reprod Health 2014;46(2):73–81. [PubMed: 24684480]

[45]. Goldstein RL, Upadhyay UD, Raine TR. With pills, patches, rings, and shots: who still uses condoms? A longitudinal cohort study. J Adolesc Health 2013;52(1):77–82. [PubMed: 23260838]

[46]. Sayegh MA, Fortenberry JD, Shew M, Orr DP. The developmental association of relationship quality, hormonal contraceptive choice and condom non-use among adolescent women. J Adolesc Health 2006;39(3):388–95. [PubMed: 16919801]

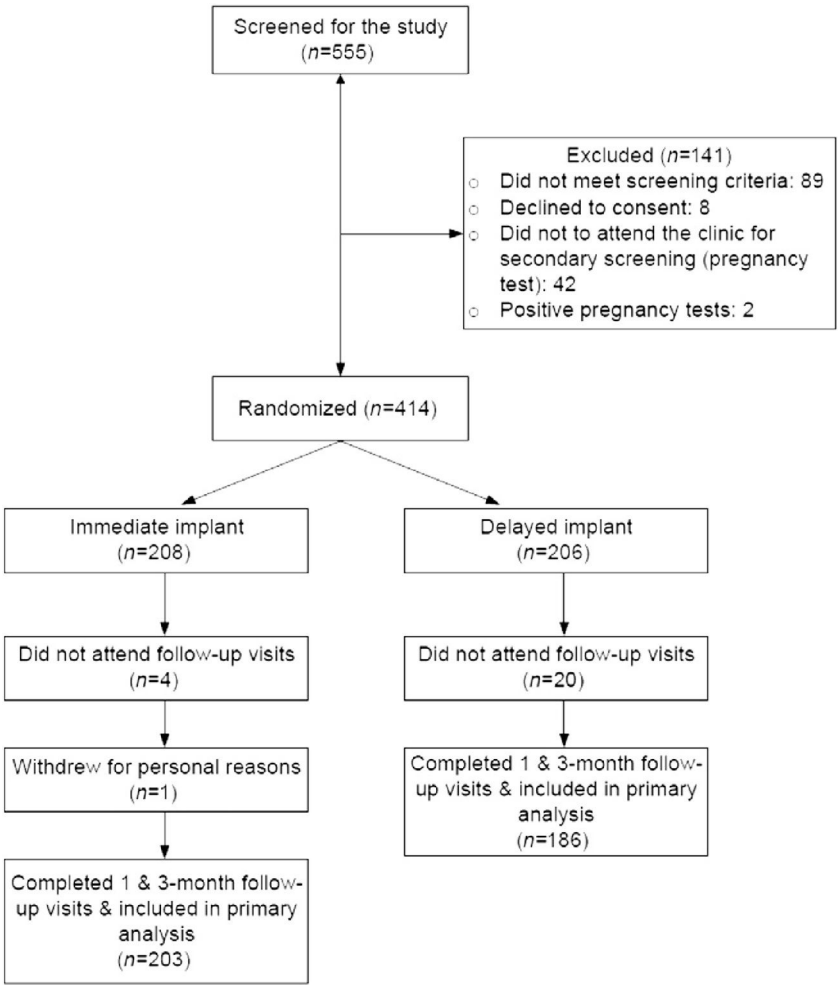

Fig. 1.
Enrollment and follow-up of study participants.

Table 1

Participant characteristics at baseline by study arm for all randomized participants (*n*=414), Sino-implant (II) Study, Kingston, Jamaica.

Characteristic	Immediate Implant (*n*=208) Frequency (%)	Delayed Implant (*n*=206) Frequency (%)
Age in years, median (interquartile range)	25 (22–30)	25 (21–30)
Parity, median (interquartile range)	2 (1–3)	2 (1–3)
Education		
Did not complete high school	65 (31.2)	64 (31.1)
Completed high school	100 (48.1)	89 (43.2)
Beyond high school	43 (20.7)	53 (25.7)
Marital status		
Single, never married	137 (65.9)	155 (75.2)
Common law/living together	58 (27.9)	43 (20.9)
Married	10 (4.8)	6 (2.9)
Divorced, separated, widowed	3 (1.4)	2 (1.0)
4 or more alcoholic drinks in 1 day in the past week		
Yes	14 (7.3)	7 (3.7)
No	179 (92.7)	183 (96.3)
Ever received money or gifts in exchange for sex		
Yes	11 (5.3)	13 (6.3)
No	195 (94.7)	193 (93.7)
Ever used a contraceptive implant		
Yes	5 (2.4)	5 (2.4)
No	203 (97.6)	201 (97.6)
Contraception in the past month[a]		
None	54 (26.0)	47 (22.8)
Male condom	120 (57.7)	107 (51.9)
Injection (DMPA)	19 (9.1)	16 (7.8)
Pill	26 (12.5)	44 (21.4)
Other	35 (16.8)	37 (18.0)
Positive test for PSA		
Yes	47 (22.6)	56 (27.2)
No	161 (77.4)	150 (72.8)
Self-reported unprotected sex in the past 2 days		
Yes	36 (17.3)	29 (14.1)
No	172 (82.7)	177 (85.9)
Self-reported unprotected sex in the past week		
Yes	47 (23.4)	46 (23.3)
No	154 (76.6)	151 (76.7)

[a]Participant can report more than one method.

Table 2

Measures of unprotected sex at each follow-up visit by study arm, Sino-implant (II) Study, Kingston, Jamaica.

	Immediate Implant	Delayed Implant	
	Frequency (%)	Frequency (%)	PR (95% CI)
Primary outcome:			
Positive test for PSA			
1 month	53 (26.1)	40 (20.2)	1.3 (0.9–1.9)
3 months	52 (25.6)	43 (23.1)	1.1 (0.8–1.6)
Secondary outcomes:			
Self-reported unprotected sex in the past 2 days			
1 month	44 (21.7)	24 (12.2)	1.8 (1.1–2.8)
3 months	35 (17.2)	21 (11.3)	1.5 (0.9–2.5)
Self-reported unprotected sex in the past week			
1 month	62 (31.0)	39 (20.5)	1.5 (1.1–2.1)
3 months	54 (27.3)	33 (18.4)	1.5 (1.0–2.2)