Increasing long acting reversible contraceptives: The Australian Contraceptive ChOice pRoject (ACCORd) cluster randomized trial

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Conflict of Interest statement

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Condensation

A complex intervention involving training family physicians in effectiveness-based contraceptive counselling and providing family physicians with access to rapid-referral LARC insertion clinics increases LARC uptake

Short title

Increasing LARC uptake: the ACCORd cluster RCT

AJOG at a glance

Why was the study conducted?

- LARCs (long-acting reversible contraceptives) are the most effective form of reversible contraception
- Uptake of LARC remains low
- The Australian Contraceptive ChOice pRoject (ACCORd) cluster randomized controlled trial investigated the impact of a complex family physician intervention on the uptake of LARCs

What are the key findings?

- Training family physicians in effectiveness-based contraception counselling and providing rapid LARC insertion clinics increased LARC uptake in the intervention group compared with control

What does this study add to what is already known?

- Training family physicians in effectiveness-based contraceptive counselling and providing rapid-referral LARC insertion clinics increases LARC uptake and may reduce unplanned pregnancies

- ACCORd is the first trial to extend efficacy demonstrated by providing LARC education to doctors in reproductive health / family planning clinics to family practice, where most contraceptives are prescribed

Keywords

LARC, IUD, contraceptive implants, intrauterine device, family physicians, education, general practice, referral, effectiveness-based, contraception, unintended pregnancy

Word count

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STRUCTURED ABSTRACT

Background

Long-active reversible contraceptives (LARCs) reduce unintended pregnancy and abortions but uptake is low. Interventions to increase uptake in family medicine settings are untested.

Objective

The Australian Contraceptive ChOice pRoject (ACCORd), adapted from the successful US Contraceptive CHOICE study, aimed to evaluate whether a complex intervention in family medicine practices resulted in increased LARC uptake by women.

Study design

This cluster randomized controlled trial was set in family practices in metropolitan Melbourne, Australia. From April 2016 to January 2017 we recruited 57 family physicians by mail invitation. Each family physician aimed to recruit at least 14 women patients. Eligible family physician worked three or more sessions per week in computerized practices. Eligible women were English speaking, sexually active, not pregnant, not planning a pregnancy in the following year, aged 16–45 years and interested in discussing contraception or in starting a new, reversible method. Using a randomization sequence with permuted bocks stratified by whether the family physician performed LARC insertion or not, family physicians were randomly assigned to a complex intervention involving training to provide structured effectiveness-based contraceptive counselling, and access to rapid referral to LARC insertion clinics. The six-hour, online educational intervention was based on the US Contraceptive CHOICE Project and adapted for the Australian context. The control family physicians received neither the educational intervention nor access to the LARC rapid referral clinics and conducted their usual contraception counselling. We used the $\chi 2$ test, adjusted for clustering and stratification by whether the family physician inserted LARCs, and binary regression models with generalized estimating equations and robust standard errors, to

compare the proportions of women who had a LARC inserted between the intervention and control groups. The primary outcome was the proportion of women with LARCs inserted at 4 weeks. Secondary outcomes included women's choice of contraceptive method, quality of life (QOL) and LARC use at 6 and 12 months. Analyses were performed according to intention-to-treat.

Results

A total of 25 intervention and 32 control family physicians recruited 307 and 433 women respectively (N=740). Within 4 weeks 19.3% of women in the intervention group and 12.9% of women in the control group had LARC inserted (RR 2.0, 95% CI 1.1 to 3.9; P=0.033). By 6 months this had risen to 44.4% and 29.3% respectively (RR 1.6, 95% CI 1.2 to 2.17; P<0.001) and by 12 months to 46.6% and 32.8% respectively (RR 1.5, 95% CI 1.2 to 2.0; P=0.0015). The levonorgestrel intra-uterine system was the most commonly chosen LARC by women in the intervention group at all time points. Differences between intervention and control groups in mean QOL scores across all domains at 6 and 12 months were small.

Conclusions

A complex intervention combining family physician training on contraceptive effectiveness counselling and rapid access to LARC insertion clinics resulted in greater LARC uptake and has the potential to reduce unintended pregnancies.

INTRODUCTION

International evidence shows that the increased use of long-acting reversible contraceptives (LARCs), defined as intrauterine devices (IUDs) and contraceptive implants, can reduce unintended pregnancy and abortion rates across all stages of a woman's reproductive life.[1-4] LARCs are the most effective reversible methods of contraception with typical-use failure rates for women of 0.05 to 0.8% in the first-year of use compared with 9% with the oral contraceptive pill and 18% with male condoms.[5] LARCs are highly acceptable to women and also have higher continuation rates than other less-effective forms of contraception.[6 7] Despite this evidence, the prescription and use of LARCs remains low. In the UK LARC prescription by FPs fell by 6% from 2014-2016.[8] In the United States, LARC uptake is increasing, but is around 14%.[9] Australia has similarly low rates with national data from 2012-2013 reporting that only 11% of women were using a LARC (6.1% for IUDs and 4.9% for implants).[10]

In the US-based Contraceptive CHOICE Project (CHOICE), a prospective cohort study of 9,526 women aged between 14-45,[11] provision of evidence-based information about all reversible contraceptive options through structured counselling as well as free provision of implants and intrauterine devices, led to a significant increase in the uptake of LARC compared to national averages. This resulted in a 20-fold reduction in unplanned pregnancy rates at three years of follow-up compared with contraceptive pill, patch or ring-users[3] and a significant reduction in abortion rates compared with the regional and national rates.[12] A subsequent randomized controlled trial, also undertaken in reproductive health clinics in the US, trained health care providers in LARC counselling and insertion but maintained normal costs to replicate real-life conditions. This study resulted in increased rates of counselling and LARC uptake in the intervention arm and reduced pregnancy rates in women attending for family planning consultations.[13]

These two studies, both undertaken in specialised clinic settings, demonstrated that improving health care provider knowledge and skills, as well as addressing some of the financial and service access barriers,[14] can impact women's uptake of LARC. However, in many countries, including Australia, specialised reproductive health services are not widely available and women rely on their family physician (FP) for contraceptive counselling and provision. While the barriers to primary care provision of LARC have been well documented,[4 14] no studies to our knowledge have tested interventions in this setting. Consequently, this study sought to compare a complex intervention on the uptake of LARC in the family medicine practice setting.

MATERIALS AND METHODS

Trial Design and Oversight

The ACCORd trial was set in metropolitan Melbourne, Australia with the FP as the unit of randomisation. Approved by the Monash University Human Research Ethics Committee: CF 14/3990-2014002066 and CF 16/188-2016000080, and conforming to CONSORT guidelines,[15] the study was conducted and reported with fidelity to the protocol described elsewhere.[16] The conduct of the trial was periodically reviewed by an independent data safety monitoring committee consisting of a statistician and two academic researchers (independent from the ACCORd study) who monitored recruitment, trial outcomes and adverse events. The authors vouch for the accuracy and completeness of the data presented.

Trial Population and Recruitment Procedures

FPs were eligible if they worked three or more sessions (half days) per week, were based at a computerized practice and had reception staff who could assist with recruiting. FP recruitment took place between May 2016 and January 2017, and all FPs who participated in

the study gave written consent at enrolment. To avoid contamination due to cross-over effects, only one FP was included per practice. Participating FPs were accredited with Continuing Professional Development points necessary to maintain professional FP qualifications and received $500 (AUD) as reimbursement for time spent on completion of the study.

Reception staff from ACCORd FPs invited women to complete an online eligibility survey that included contact details using an iPad in the waiting room. Women were eligible to participate if they were aged between 16-45, had been sexually active with a male partner in the previous six months or anticipated sexual activity in the subsequent six months, had not undergone tubal ligation or hysterectomy, had sexual partners who had not undergone a vasectomy, were neither pregnant nor anticipating a pregnancy in the following 12 months, spoke proficient English and were interested in discussing contraception or in starting a new, reversible contraceptive method.

All eligible women were contacted by telephone by an ACCORd researcher to obtain consent and complete baseline questionnaires. After enrolment, women were asked to return to their ACCORd FP within one week for a contraceptive counselling appointment. Any additional charges for this visit were covered by ACCORd to ensure that the women did not bear out-of-pocket costs for this additional visit. ACCORd did not provide coverage for the cost of individual contraceptive products.

Randomisation and Masking

The trial statistician generated a randomisation sequence with permuted blocks (block sizes of 4, 6 and 8), stratified by whether the FP performed LARC insertion (IUDs/implants) or not.[17] This sequence was then held by a research assistant who was not involved in the

ACCORD trial. When a FP was recruited, ACCORd staff contacted the research assistant to assign the FP to the next allocation in the sequence.

Interventions

FPs in the intervention arm were trained to deliver structured contraceptive counselling and given access to rapid referral to LARC insertion clinics through an online booking system. Materials from the "LARC first" (contraceptive effectiveness) online training site of the Contraceptive CHOICE project[3] were adapted to the Australian context with input from an advisory group comprising the project investigators, FPs, and consumers. Training was delivered online through a six-hour training package with additional practice visits, email, and telephone support where required. Structured contraceptive counselling[18] consisting of non-biased, scripted descriptions of all available contraceptive methods, with particular reference to the safety and efficacy of each method, was then delivered to the participating women by the intervention trained FPs. FPs also collected clinical information from the women to identify any contraindications or conditions that may influence the choice of contraception. Women were able to choose their contraception method provided that it was not medically contraindicated. The FP was then advised to screen the woman for pregnancy (history and urine pregnancy test) and chlamydia (according to clinical practice guidelines published by the Royal Australian College of General Practitioners).[19] The online training recommended ruling out pregnancy before: (a) providing a prescription for the method of choice; (b) offering "same day" insertion of the LARC method, or at a subsequent time at the FP clinic; or (c) providing an appointment for insertion of the LARC method at one of the insertion clinics. Emergency contraception was advised for women who had recent unprotected intercourse, while "quick start" contraception (i.e. commencing contraception at any time rather than at the start of the next menstrual cycle) was recommended for women in cases where pregnancy could be ruled out (as per the Faculty of Sexual and Reproductive

Healthcare guidelines).[20] In both of these cases a return appointment in three to four weeks for a LARC insertion (and a repeat pregnancy test) was also recommended.

A rapid referral pathway to a LARC insertion clinic with two local private gynecologists was implemented through an online booking system for intervention FPs who did not or chose not to perform insertions in their own rooms. Gynecologists providing these LARC insertion clinics received payment of $300 (AUD) per 3 ½ hour clinic undertaken and were free to charge patients their usual fees at these clinics.

FPs in the control group provided usual contraceptive care to women recruited to this arm and did not have access to the rapid referral LARC insertion clinics. At the conclusion of the trial, the control group of FPs were invited to undertake the online contraceptive effectiveness training.

Fidelity checking

To ensure fidelity of the counselling, a researcher (blinded to the allocation of the FP to intervention or control arm) visited FPs in both groups. During this visit, the researcher observed a single consultation and completed a checklist regarding the content of the contraceptive counselling provided to ascertain whether the counselling was structured with an emphasis on effectiveness.

Trial Measures

At baseline eligible women undertook an initial telephone based questionnaire drawn from the US Contraceptive Choice Project[3] and including the Health Literacy Questionnaire (HLQ),[21] and Medical Outcomes Survey (SF-36).[22] Further surveys were conducted online at 6 months (including the SF-36) and at 12 months (including the HLQ and SF-36). After completing each survey women were given an entry into a monthly prize draw for a $150 gift voucher.

Participating FPs and gynecologists working in the LARC insertion clinics were asked to complete a standardised data collection form at every consultation involving an ACCORd participant.

Primary and secondary outcomes

The primary outcome was the proportion of women who had a LARC inserted within 4 weeks of the initial contraceptive consultation with their FP. Secondary outcomes included women's choice of contraceptive method, quality of life and LARC use at 6 and 12 months. These outcomes were measured using data sourced from the standardised data collection forms and from the 6 and 12 month surveys.

Statistical analysis

Current LARC use increased from 2.3% to 11% of all contraceptives use in Australia over a 13 year time frame.[10 23] A British study estimated that if 5% of British women who used oral contraceptives used LARC instead, the decrease in contraceptive failure would result in 7,500 annual unplanned pregnancies.[24] Therefore, we chose an effect size of 10%. We estimated that we would require 24 FPs and 24 women per FP in each of the two study arms (intervention and control) to detect a 10% increase in the LARC insertion rate, with 80% power and a significance level of 5% allowing for stratification according to whether or not FPs inserted LARCs and a clustering effect (intracluster correlation (ICC)) of 0.05. This corresponds to the maximum ICC for variables associated with FP–patient encounters in a recent cluster RCT [25] and other FP-specific studies.[26] We aimed to recruit 27 FPs and 27 women per FP in each of the two study arms to allow for up to a 10% drop-out among FPs and a 10% drop-out among women.

We calculated counts and proportions for descriptive characteristics of FPs and women at baseline. We used the $\chi 2$ test, adjusted for clustering and stratification by whether the FP

inserted LARCs, and binary regression models with generalized estimating equations and robust standard errors, to compare the proportions of women who had a LARC inserted (the primary outcome) between the intervention and control groups for women who had outcome data available. The outcomes for women were analysed according to their randomized group (intention-to-treat analysis). This method was also applied to the secondary outcomes of LARC use at 6 and 12 months. Linear regression models also adjusting for study design were used to compare mean QOL scores between groups. We conducted sensitivity analyses by adjusting for the following variables: FP sex, FP age group, women's age group, parity and use of LARC at baseline. Additional sensitivity analyses were carried out assuming that women with missing outcome data were not missing at random. For these analyses, we used multiple imputation under plausible missing data scenarios - women with missing outcome data had (1) the same probability of the outcome as those from the same arm; (2) the same probability of the outcome as those from the control arm; (3) the same probability of the outcome as those from the intervention arm; (4) no LARC inserted. Twenty imputation datasets were created in each analysis and the results were combined using Rubin's rules. In the binary regression models we investigated whether the effect of the intervention varied across subgroups defined by age, parity, use of LARC at baseline, marital status, socioeconomic status, education, previous unintended pregnancy and previous abortion using interaction terms. All analyses were carried out using SAS v9.4.

Stakeholder involvement

Prior to commencement of recruitment and prior to final ethics submission, the study tools (FP surveys) were piloted among five FPs who provided suggestions for amendment. FPs were also asked to assess the burden of intervention and the time required to participate in the study.

RESULTS

Trial Sites and Participants

From April 2016 to May 2017, 43 FPs were randomly allocated to the intervention group (with 25 subsequent withdrawals) and 44 to the control group (with 23 subsequent withdrawals). A total of 25 intervention FPs recruited at least one participant, as did 32 control FPs (Figure 1). The characteristics of the FPs were well-balanced between the intervention and control groups (Table 1). The majority of the FPs were females, aged 35 to 54 and inserted implants but not IUDs. Most FPs (81%) had 10 or more years of experience. Recognised training in contraception had been undertaken by 25% of FPs, and 40% of intervention FPs and 34% of control FPs also having specific training in IUD insertion (Table 1).

Between June 2016 and July 2017, intervention FPs recruited 410 women (103 women initially expressed an interest in the study but did not consent) and control FPs recruited 622 women (189 women initially expressed an interest in the study but did not consent), resulting in 307 and 433 women in the intervention and control arms respectively (N=740). The characteristics of the women were also well-balanced between the two groups (Table 1). This balance was retained among women with available data from the Standardised Data Collection Forms and from the 6 and 12 month survey. Most women were aged under 35 years, had no children and were not currently using a LARC. The rate of cohort retention was 71% in both groups.

Primary and Secondary Outcomes

Within 4 weeks of the contraceptive counselling consultation 8% more women in the intervention group than in the control group had had a LARC inserted (95% confidence interval (CI), 1.5 to 15.4 P=0.018) (Table 2), with ICC of 0.13.

LARC uptake continued to rise with time at 6 and 12 months with a greater proportion of women in the intervention group (44% and 47%, respectively) currently using a LARC compared to the control group (29% and 33%, respectively) (Table 2).

The levonorgestrel IUS was the most commonly chosen LARC in the intervention group and the etonogestrel implant in the control group at the 4 week, 6 month and 12 month time points. (Table 3). None of the interaction tests indicated a differential effect of the intervention across subgroups defined by age, parity, use of LARC at baseline, marital status, socioeconomic status, education, previous unintended pregnancy or previous abortion (Supplementary Table A1).

The results of the primary outcome analysis were similar, although the effects were smaller, when covariates were adjusted for or when missing data were imputed under various assumptions. The P-values for the comparison of binary outcomes were similar when calculated using the $\chi 2$ test, adjusted for clustering and stratification or using binary regression with GEE for all outcomes except for insertion at 4 weeks where the P-values were 0.20 and 0.03, respectively (Supplementary Table A2).

The differences between intervention and control groups in mean QOL scores across all domains at 6 and 12 months were small and unlikely to be of practical importance or clinical significance despite two of the comparisons being statistically significant. The statistically significant differences did not persist at 12 months (Table 4).

Process Data

Fidelity checks were completed for nine intervention FPs and 12 control FPs. Initiation of structured efficacy-based contraceptive counselling was observed for 44% of the intervention FPs (n=4) compared with 8% of the control FPs (n=1). Also, the data monitoring committee met every three months during the recruitment and data collection phases of the study. No unexpected complications nor adverse-effects were noted in either group.

STRUCTURED DISCUSSION / COMMENT

Principal Findings

The ACCORd trial results demonstrate that a family medicine practice based intervention consisting of online training in structured effectiveness-based contraceptive counselling and the provision of a rapid referral pathway to LARC insertion clinics results in increased LARC uptake. Women participants of FPs who had received these interventions were significantly more likely to have had a LARC inserted 4 weeks from receipt of contraceptive counselling by their FP. This number increased by 6 months and increased further at 12 months.

Results (in context of what is known)

While ACCORd was modelled on the successful CHOICE study in the USA,[11] our intervention differed from CHOICE in that it did not focus on reducing the cost of contraceptive methods. This suggests that in contexts such as Australia, where LARC uptake is poor despite universal health coverage and subsidised contraception, the cost of contraception for an individual woman may not impact on contraceptive decision-making as much as receiving structured effectiveness-based contraceptive counselling and the availability of a timely pathway to LARC insertion. Indeed the effect of the intervention did not differ by socioeconomic status.

Lack of FP training in LARCs and LARC insertion has been identified as a barrier to increasing LARC uptake.[14] Even with training, FPs often face difficulties sustaining practice in LARC insertion, with one study finding that only about 30% of those trained in LARC insertions continued to insert 12 or more devices per year, the minimum suggested by experts to maintain skill levels.[27] The ACCORd intervention did not train FPs to insert LARCs. Despite this it still achieved increased rates of LARC uptake. This may be because the ACCORD intervention addressed other barriers that have been well described in the literature such as tackling the myths and misconceptions concerning LARCs held by both FPs (through the training) and women (through structured effectiveness focused counselling) and by making LARC insertion more accessible through rapid referral pathways to insertion clinics.

Clinical Implications

Our findings are important as ACCORd is the first trial to extend the efficacy demonstrated by providing LARC education to doctors in reproductive health and family planning clinics[9] to a new and important site - family practice. Extending LARC education to primary care can assist the large number of women who access general practice for their health care. In many countries internationally, there is a paucity of specialised contraceptive clinics, and general practice is the main provider of women's sexual and reproductive health services, particularly contraception.

Research Implications

While the trial demonstrated that a complex intervention involving training FPs to deliver structured effectiveness-based contraceptive counselling and making available timely access to LARC insertion clinics is effective at increasing LARC uptake, we cannot identify which aspect of the intervention mattered the most. While LARC uptake increased in both

intervention and control groups the intervention group had higher uptake of the hormonal IUS. This may indicate the importance of timely access to insertion clinics especially since only 44% of intervention fidelity checks witnessed the delivery of structured efficacy based contraceptive counselling.

Strengths and Limitations

The strengths of this study include the evaluation of the intervention in routine general practices and examination of the sustainability of the effects after the availability of the intervention had ceased. We undertook randomization of doctors rather than women in our cluster randomized controlled trial. This reduced contamination which would have occurred if women had been individually randomized, as individual women in the same practice may have been in different arms of the study.

The intervention effect and the high cohort retention rate are also strengths providing us with the opportunity to demonstrate the longevity of the effect of the ACCORd intervention. While the use of LARCs in our population of women participants was lower at baseline (13%) than a recently reported population based survey involving a younger population (19%),[28] it was similar to another Australian study which reported 11% LARC use.[10] At six months, 44% of our intervention group and 29% of our control group were using LARCs, reflecting an increase in LARC use over both groups (but significantly higher in the intervention group), and a higher proportion of current LARC users than recently reported. At 12 months the increase was sustained with 47% of women in the intervention group and 33% in the control group. Longer follow up would have allowed us to determine if this rise in LARC uptake persisted beyond one year.

Our trial had several limitations. Masking of doctors and women during implementation was not feasible and because women's outcomes were self-reported there may have been some bias responding to the survey questions.

Withdrawal of both FPs (58% in the intervention group and 52% in the control group) and women participants (29% across both groups) from the study was higher than the 10% anticipated. This may reflect the difficulty some FPs had completing a six-hour online learning module, an inability of participants to spend the required time to complete the study, and/or poor incentives for both FPs and women participants. Future research should focus on determining whether other approaches to training FPs which are less time consuming such as academic detailing or involvement in an online community of practice achieve the same outcomes.

We originally designed the study with 24 FPs in each arm, and each FP recruiting 24 women. However, once recruitment began it was apparent that some FPs would not reach the target of 24 women in the required time. For some FPs this was because their patient population did not include many women of reproductive age. This was particularly the case for male FPs and female FPs who were themselves over 45 years. To compensate we decided to recruit more FPs, and we also allowed FPs (who were able) to recruit more than 24 women.

Setting one of the primary outcomes as LARC insertion at four weeks was problematic for some women as there was a delay in returning to the FP for a contraceptive consultation, and a further delay if LARC referral / insertion was instigated. A more clinically meaningful outcome may have been LARC use at 6 months or 12 months, to reflect LARC insertion and retention over time.

Our sample of FPs as well as their women patients were highly educated. We anticipated that FPs interested in contraception would be over-represented in our study and indeed 25% of

ACCORd FPs had undertaken additional training in contraception. This rate was however well balanced across both intervention and control groups, making the effect of our intervention even more compelling. Non-inclusion of women who spoke limited English may affect the generalizability of our findings to women of non-English speaking backgrounds. Additionally, our sample of women was from the metropolitan area, and rural women may face greater challenges with access to LARC insertion. The small number of male FPs in our study may impact on the generalizability of the ACCORd intervention in general practice settings where there are larger proportions of male practitioners.

The P-value for the outcome insertion at 4 weeks differed when calculated by the $\chi 2$ test, adjusted for clustering and stratification, and binary regression model with GEE. However, the $\chi 2$ test can be less powerful than binary regression and so may not detect a difference if it exists and the binary regression model will provide an unbiased estimate with appropriate confidence interval coverage. Hence, we consider the results from the binary regression model to be more informative.[29 30]

Conclusions

In conclusion the provision of training to FPs in structured efficacy- focussed contraceptive counselling together with providing FPs with a rapid referral pathway to LARC insertion clinics results in increased LARC uptake. Implementation of this approach in family medicine practice settings more broadly, particularly in contexts where free contraception is not feasible, and specific sexual and reproductive health services are either not available or accessible could lead to reductions in unplanned pregnancies and abortion.

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Contributors

DM, KB, AT, JL, KMG, MH, KM & JP contributed to the design of the trial. All authors contributed to the development of the study tools, the interpretation of results and writing and approval of the final paper. KMG advised on the design of the study, oversaw randomisation, and undertook analyses.

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Ethics

Approved by the Monash University Human Research Ethics Committee: CF 14/3990-2014002066 and CF 16/188-2016000080

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591 **Table 1: Characteristics of family physicians and women participants**

592

		Intervention n (%)	Control n (%)	Total
Family physicians				
Number of family physicians		25	32	57
Gender	Male	2 (8.0)	4 (12.5)	6
	Female	23 (92.0)	28 (87.5)	51
Age group	25 to 34	3 (12.0)	2 (6.3)	5
	35 to 54	17 (68.0)	24 (75.0)	41
	55 and over	5 (20.0)	6 (18.8)	11
Inserts IUDs*	No	22 (88.0)	27 (84.4)	47
	Yes	3 (12.0)	5 (15.6)	8
Inserts implants	No	7(28.0)	10 (31.3)	17
	Yes	18 (72.0)	22 (68.8)	40
Number of implants inserted each month	1 to 4	3 (12.0)	3 (9.4)	6
	5 to 9	1 (4.0)	4 (12.5)	5
	10 or more	21 (84.0)	25 (78.1)	46
Specific training in contraception	No	19 (76.0)	24 (75.0)	43
	Yes	6 (24.0)	8 (25.0)	14
Trained to insert IUDs*	No	15 (60.0)	21 (65.6)	36
	Yes	10 (40.0)	11 (34.4)	21
Women participants				
Number of participants		307	433	740

Age	16 to 24 years	104 (33.9)	163 (37.6)	267
	25 to 34 years	111 (36.2)	173 (40.0)	284
	35 to 45 years	92 (30.0)	97 (22.4)	189
Parity	0	207 (67.4)	313 (72.3)	520
	1	24 (7.8)	32 (7.4)	56
	2	53 (17.3)	71 (16.4)	124
	3 or more	23 (7.5)	17 (3.9)	40
LARC† use at baseline#	No	266 (87.2)	379 (87.5)	645
	Yes	39 (12.8)	54 (12.5)	93
Marital status‡	Married/de facto	133 (43.5)	184 (42.5)	317
	Single	173(56.5)	249 (57.5)	422
Household income‡	≤$600 per week	75 (30.4)	126 (35.3)	201
	> $600 per week	172 (69.6)	231 (64.7)	403
Education	Completed less than Year 12	99 (32.2)	144 (33.3)	243
	Completed Year 12 or more	208 (67.8)	289 (66.7)	497
Previous unintended pregnancy	No	249 (81.1)	363 (83.8)	612
	Yes	58 (18.9)	70 (16.2)	128
Previous abortion	No	267 (87.0)	390 (90.1)	657
	Yes	40 (13.0)	43 (9.9)	83

593

594 *IUD: Intrauterine device

595 † LARC: Long-acting reversible contraceptives

596 ‡ missing data for some women

597 **Table 2: Outcomes at 4 weeks, 6 months and 12 months***

598

		Number of women with information available		Number (%) with outcome					
		Intervention group	**Control Group**	**Intervention group n (%)**	**Control Group n (%)**	**Prevalence ratio (95% CI) †**	**P-value**	**Difference (95% CI) †**	**P-value‡**
Outcomes at 4 weeks	**LARC§insertions**	248	378	48 (19.3%)	45 (12.9%)	2.0 (1.1 to 3.9)	0.033	8.4 (1.5 to 15.4)	0.018
Outcomes at 6 months	**LARC§use at any time in 6 months**	214	311	106 (49.5%)	99 (31.8%)	1.7 (1.3 to 2.2)	<0.001	21.8 (13.3 to 30.2)	<0.001
	Currently using a LARC§	214	311	95 (44.4%)	91 (29.3%)	1.6 (1.2 to 2.2)	<0.001	18.9 (10.2 to 27.7)	<0.001

Outcomes at 12 months	**LARC[§] use at any time in 12 months**	219	308	113 (51.6%)	108 (35.1%)	1.6 (1.2 to 2.0)	<0.001	20.0 (10.6 to 29.5)	<0.001
	Currently using a LARC[§]	219	308	102 (46.6%)	101 (32.8%)	1.5 (1.2 to 2.0)	0.0015	16.7 (7.4 to 26.0)	<0.001

*Adjusted for clustering by the family physician and stratified by whether the family physician inserted long-acting reversible contraceptives

† CI: Confidence intervals

‡The statistical test in the tables is the Wald Chi-square test from the fitted binary regression models with generalized estimating equation.

§ LARC: Long-acting reversible contraceptives

Table 3: Choice of contraceptive method

		Hormone IUS* n (%)	**Cu IUD**† n (%)	**Implant** n (%)	**Injection** n (%)	**OCP**‡ n (%)	**Ring** n (%)	**Condoms** n (%)	**Withdrawal** n (%)	**Nothing** n (%)	**Other** n (%)	**Not answered** n (%)
Contraception recorded at baseline for women with data available from Standardised Data Collection Forms§	**Intervention (n=248)**		16 (6.5)	13 (5.2)	3 (1.2)	114 (46.0)	4 (1.6)	61 (24.6)	14 (5.6)	34 (13.7)	9 (3.6)	
	Control (n=378)		16 (4.2)	29 (7.7)	5 (1.3)	173 (45.8)	1 (0.3)	87 (23.0)	9 (2.4)	65 (17.2)	7 (1.9)	
Contraception method recorded within 4 weeks of initial contraceptive counselling consultation‖	**Intervention (n=248)**	39(15.7)	2 (0.8)	28 (11.3)	3 (1.2)	94 (37.9)	3 (1.2)	30 (12.1)	2 (0.8)	33 (13.3)	5 (2.0)	9 (3.6)
	Control (n=378)	28 (7.4)	4 (1.1)	45 (11.9)	4(1.1)	162 (42.3)	2 (0.5)	64 (16.9)	2 (0.5)	58 (15.3)	2 (0.5)	7 (1.9)

Current contraceptive method utilised at 6 months ¶	**Intervention (n=214)**	65 (30.4)	5 (2.3)	25 (11.7)	3 (1.4)	54 (25.2)	1 (0.5)	74 (34.6)	31 (14.5)	4 (1.9)	5 (2.3)	
	Control (n=311)	36 (11.6)	8 (2.6)	47 (15.1)	3 (1.0)	122 (39.2)	3 (1.0)	101 (32.5)	46 (14.8)	7 (2.3)	3 (1.0)	
Current contraceptive methods utilised at 12 months # §	**Intervention (n=219)**	63 (28.8)	6 (2.7)	26 (11.9)	4 (1.8)	68 (31.1)	0 (0)	67 (30.6)	-	4 (1.8)	4 (1.8)	
	Control (n=308)	39 (12.7)	11 (3.6)	49 (15.9)	2 (0.7)	106 (34.4)	2 (0.7)	98 (31.8)	-	15 (4.9)	3 (1.0)	

*IUS: Intrauterine system †IUD: Intrauterine device ‡OCP: oral contraceptive pill (combined or progestogen only)

§ Note 78% of women had the baseline survey completed after the initial FP visit. For these women baseline contraception information was derived from the data collected at this initial visit. Only one form of contraception was recorded at these visits however the baseline questionnaire allowed for multiple forms. To reconcile the two data sources women have been assigned the most effective method if they recorded use of multiple methods. The baseline questionnaire also did not differentiate between hormonal and copper intrauterine devices.

||Note only one form of contraception recorded at FP visits

¶ Note women could record multiple methods # Women not asked whether they were currently using withdrawal.

Table 4: Participant quality of life (QOL scales) at baseline, 6 and 12 months

	Baseline	6 months			12 months		
Scale	Mean (SD)	Mean (SD)	Difference (95% CI) *	P-value	Mean (SD)	Difference (95% CI) *	P-value
Physical functioning							
Intervention group	93 (11.7)	94 (10.7)	2.4 (0.04 to 4.7)	0.05	93 (12)	1.3 (-1.4 to 4.1)	0.34
Control group	93 (14.9)	91 (16.9)			91 (17.6)		
Role limitations due to physical health							
Intervention group	73 (38.9)	87 (27.7)	5.4 (-0.2 to 1.1)	0.06	87 (29.5)	2.2 (-2.7 to 7.2)	0.37
Control group	76 (35.3)	83 (31.6)			84 (32.4)		
Role limitations due to emotional problems							
Intervention group	73 (36.6)	74 (37.8)	1.3 (-5.2 to 7.8)	0.70	75 (36)	0.6 (-4.7 to 5.9)	0.83
Control group	75 (36.4)	73 (39.0)			74 (38.5)		
Energy/fatigue							
Intervention group	55 (19.3)	51 (19.9)	0.4 (-2.6 to 3.3)	0.81	51 (21.1)	-0.5 (-4.1 to 3.2)	0.80
Control group	52 (20.8)	50 (19.8)			50 (20.6)		

Emotional well-being							
Intervention group	76 (15.1)	71 (17.2)	2.3 (-0.2 to 4.8)	0.07	72 (16.7)	0.8 (-1.9 to 3.5)	0.56
Control group	75 (16.6)	69 (19.1)			70 (18.3)		
Social functioning							
Intervention group	82 (18.7)	84 (18.1)	2.3 (-1.6 to 6.1)	0.24	82 (19.9)	-0.1 (-3.0 to 2.8)	0.94
Control group	82 (19.6)	82 (20.3)			82 (20.2)		
Pain							
Intervention group	74 (21.5)	81 (18.4)	2.2 (-0.6 to 5.0)	0.13	78 (21.9)	-0.3 (-3.1 to 2.4)	0.81
Control group	76 (21.7)	79 (20.7)			79 (21.0)		
General health							
Intervention group	71 (19.1)	68 (18.4)	2.2 (1.2, 3.2)	<0.0001	67 (19.4)	0.7 (-2.9 to 3.3)	0.62
Control group	70 (19.8)	66 (19.6)			66 (19.5)		

* adjusted for clustering by family physician, stratification (whether family physician inserts long-acting reversible contraceptives and baseline values

Note: Q23 of DF-36 which contributes to the Energy/Fatigue scale was not included in the survey.

Results were similar when missing data are imputed assuming women with missing outcome data have similar outcomes as (1) those from same group, or (2) those in the control group

Supplementary Tables

Table A1: Subgroup analyses. Insertion of long-acting reversible contraceptives at 4 weeks

			Intervention		Control			
Subgroup variable	Subgroup	Number of women with information available	Yes n (%)	No n (%)	Number of women with information available	Yes n (%)	No n (%)	P-value for interaction between intervention and subgroup variable
Age group	16 to 24	87	20 (23.0)	67 (77.0)	142	17 (12.0)	125 (88.0)	0.61
	25 to 34	84	17 (20.2)	67 (79.8)	153	23 (15.0)	130 (85.0)	
	35 to 45	77	11 (14.3)	66 (85.7)	83	5 (6.0)	78 (94.0)	
Parity	No children	164	33 (20.1)	131 (79.9)	275	36 (13.1)	239 (86.9)	0.08
	1 child	19	2 (10.5)	17 (89.5)	24	4 (16.7)	20 (83.3)	

	2 children	44	7 (15.9)	37 (84.1)	63	5 (7.9)	58 (92.1)	
	3+ children	21	6 (28.6)	15 (71.4)	16	0 (0.0)	16 (100.0)	
Marital status	Married/de facto	103	18 (17.5)	85 (82.5)	160	14 (8.8)	146 (91.3)	0.23
	Single	144	30 (20.8)	114 (79.2)	218	31 (14.2)	187 (85.8)	
Household income	≤$600 per week	59	10 (16.9)	49 (83.1)	110	18 (16.4)	92 (83.6)	0.31
	>$600 per week	140	29 (20.7)	111 (79.3)	201	21 (10.4)	180 (89.6)	
Highest level of education	Year 12 or below	84	18 (21.4)	66 (78.6)	127	18 (14.2)	109 (85.8)	0.64
	Beyond Year 12	164	30 (18.3)	134 (81.7)	251	27 (10.8)	224 (89.2)	
Previous unintended pregnancy	No	200	38 (19.0)	162 (81.0)	319	33 (10.3)	286 (89.7)	0.18
	Yes	48	10 (20.8)	38 (79.2)	59	12 (20.3)	47 (79.7)	
Previous abortion	No	214	40 (18.7)	174 (81.3)	340	36 (10.6)	304 (89.4)	0.22
	Yes	34	8 (23.5)	26 (76.5)	38	9 (23.7)	29 (76.3)	

Using LARC* at baseline	No	219	179 (81.7)	40 (18.3)	333	33 (9.9)	300 (90.1)	0.82
	Yes	29	8 (27.6)	21 (72.4)	45	12 (26.7)	33 (73.3)	

***LARC: Long-acting reversible contraceptives**

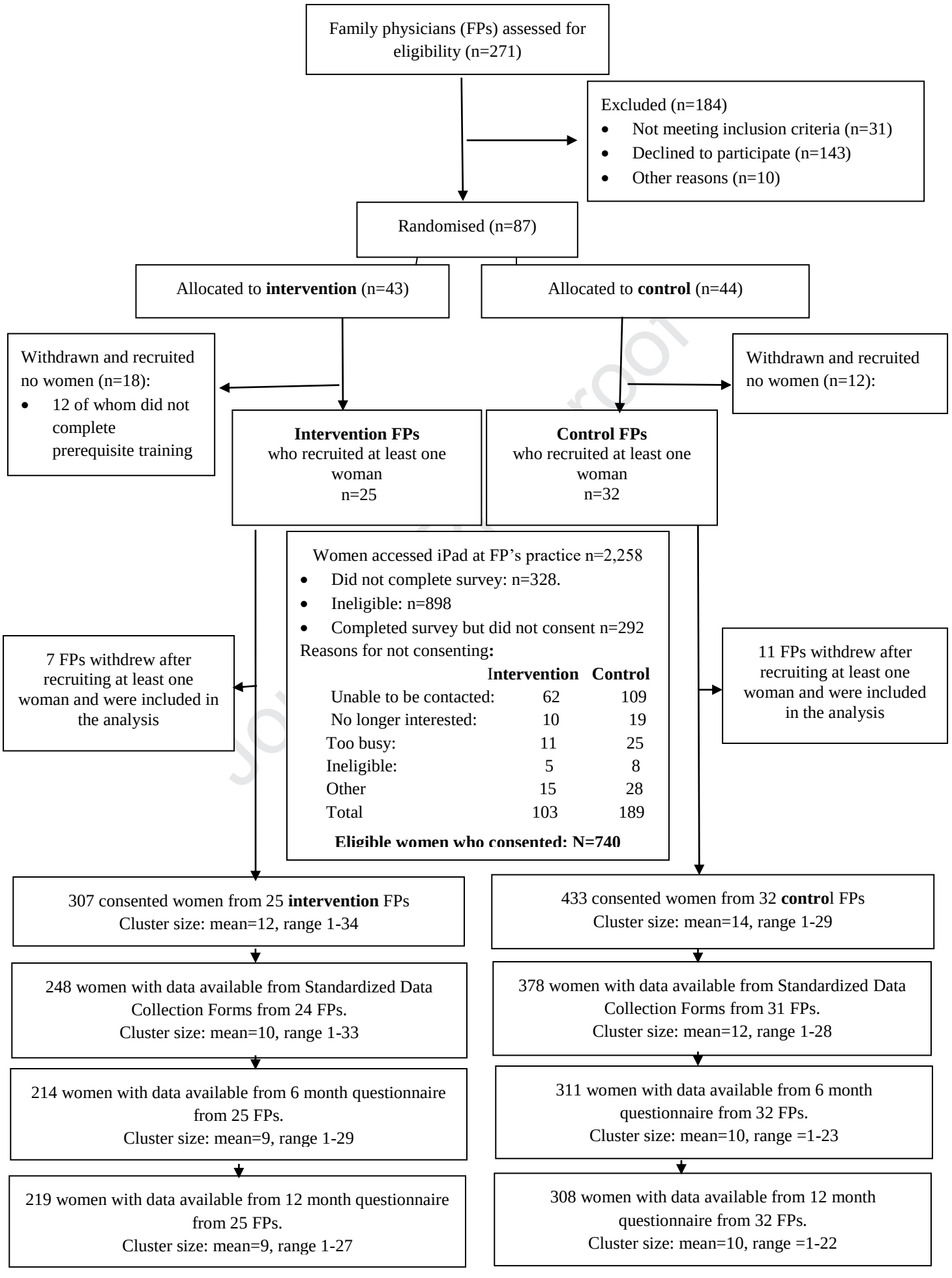
Table A2: P-values from Chi-Squared Mantel-Haenszel analysis (MHA) and Binary regression models with Generalized Estimating Equations (GEE) for Outcomes

		GEE P-value	MHA P-value
Outcomes at 4 weeks after initial consult	Referred for LARC* insertion	0.0001	0.0002
	LARC insertions	0.033	0.20
Outcomes at 6 months	LARC use at any time in 6 months	<0.0001	0.00053
	Currently using a LARC	0.0007	0.003
Outcomes at 12 months	LARC use at any time in 12 months	0.0002	0.0011
	Currently using a LARC	0.0015	0.0086

LARC: Long-acting reversible contraceptives

TABLES AND FIGURE LEGENDS

Supplementary Tables


Family physicians (FPs) assessed for eligibility (n=271)
Excluded (n=184)
Not meeting inclusion criteria (n=31)
Declined to participate (n=143)
Other reasons (n=10)
Randomised (n=87)
Allocated to intervention (n=43)
Allocated to control (n=44)
Withdrawn and recruited no women (n=18):
12 of whom did not complete prerequisite training
Withdrawn and recruited no women (n=12):
Intervention FPs who recruited at least one woman n=25
Control FPs who recruited at least one woman n=32
Women accessed iPad at FP's practice n=2,258
Did not complete survey: n=328.
Ineligible: n=898
Completed survey but did not consent n=292
Reasons for not consenting:
Intervention Control
Unable to be contacted: 62 109
No longer interested: 10 19
Too busy: 11 25
Ineligible: 5 8
Other 15 28
Total 103 189
Eligible women who consented: N=740
7 FPs withdrew after recruiting at least one woman and were included in the analysis
11 FPs withdrew after recruiting at least one woman and were included in the analysis
307 consented women from 25 intervention FPs
Cluster size: mean=12, range 1-34
433 consented women from 32 control FPs
Cluster size: mean=14, range 1-29
248 women with data available from Standardized Data Collection Forms from 24 FPs.
Cluster size: mean=10, range 1-33
378 women with data available from Standardized Data Collection Forms from 31 FPs.
Cluster size: mean=12, range 1-28
214 women with data available from 6 month questionnaire from 25 FPs.
Cluster size: mean=9, range 1-29
311 women with data available from 6 month questionnaire from 32 FPs.
Cluster size: mean=10, range =1-23
219 women with data available from 12 month questionnaire from 25 FPs.
Cluster size: mean=9, range 1-27
308 women with data available from 12 month questionnaire from 32 FPs.
Cluster size: mean=10, range =1-22