Journal Pre-proof

1 # Increasing long acting reversible contraceptives:

2 # The Australian Contraceptive ChOice pRoject

3 # (ACCORd) cluster randomized trial

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21 **Conflict of Interest statement**

41   **Clinical Trial Registration**

42   Australian and New Zealand Clinical Trial Registry ANZCTR 12615001346561, 10/12/2015

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62   **Condensation**

63   A complex intervention involving training family physicians in effectiveness-based

64   contraceptive counselling and providing family physicians with access to rapid-referral

65   LARC insertion clinics increases LARC uptake

66   **Short title**

67   Increasing LARC uptake: the ACCORd cluster RCT

68   **AJOG at a glance**

69   Why was the study conducted?

70   • LARCs (long-acting reversible contraceptives) are the most effective form of

71   reversible contraception

72   • Uptake of LARC remains low

73   • The Australian Contraceptive ChOice pRoject (ACCORd) cluster randomized

74   controlled trial investigated the impact of a complex family physician intervention on

75   the uptake of LARCs

76   What are the key findings?

77   • Training family physicians in effectiveness-based contraception counselling and

78   providing rapid LARC insertion clinics increased LARC uptake in the intervention

79   group compared with control

80   What does this study add to what is already known?

81   • Training family physicians in effectiveness-based contraceptive counselling and

82   providing rapid-referral LARC insertion clinics increases LARC uptake and may

83   reduce unplanned pregnancies

84   • ACCORd is the first trial to extend efficacy demonstrated by providing LARC

85   education to doctors in reproductive health / family planning clinics to family

86   practice, where most contraceptives are prescribed

87 **Keywords**

88 LARC, IUD, contraceptive implants, intrauterine device, family physicians, education,

89 general practice, referral, effectiveness-based, contraception, unintended pregnancy

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97   **STRUCTURED ABSTRACT**

98   **Background**

99   Long-active reversible contraceptives (LARCs) reduce unintended pregnancy and abortions

100   but uptake is low. Interventions to increase uptake in family medicine settings are untested.

101   **Objective**

102   The Australian Contraceptive ChOice pRoject (ACCORd), adapted from the successful US

103   Contraceptive CHOICE study, aimed to evaluate whether a complex intervention in family

104   medicine practices resulted in increased LARC uptake by women.

105   **Study design**

106   This cluster randomized controlled trial was set in family practices in metropolitan

107   Melbourne, Australia. From April 2016 to January 2017 we recruited 57 family physicians by

108   mail invitation. Each family physician aimed to recruit at least 14 women patients. Eligible

109   family physician worked three or more sessions per week in computerized practices. Eligible

110   women were English speaking, sexually active, not pregnant, not planning a pregnancy in the

111   following year, aged 16–45 years and interested in discussing contraception or in starting a

112   new, reversible method. Using a randomization sequence with permuted bocks stratified by

113   whether the family physician performed LARC insertion or not, family physicians were

114   randomly assigned to a complex intervention involving training to provide structured

115   effectiveness-based contraceptive counselling, and access to rapid referral to LARC insertion

116   clinics. The six-hour, online educational intervention was based on the US Contraceptive

117   CHOICE Project and adapted for the Australian context. The control family physicians

118   received neither the educational intervention nor access to the LARC rapid referral clinics

119   and conducted their usual contraception counselling. We used the $\chi 2$ test, adjusted for

120   clustering and stratification by whether the family physician inserted LARCs, and binary

121   regression models with generalized estimating equations and robust standard errors, to

122   compare the proportions of women who had a LARC inserted between the intervention and

123   control groups. The primary outcome was the proportion of women with LARCs inserted at 4

124   weeks. Secondary outcomes included women's choice of contraceptive method, quality of

125   life (QOL) and LARC use at 6 and 12 months. Analyses were performed according to

126   intention-to-treat.

127   **Results**

128   A total of 25 intervention and 32 control family physicians recruited 307 and 433 women

129   respectively (N=740). Within 4 weeks 19.3% of women in the intervention group and 12.9%

130   of women in the control group had LARC inserted (RR 2.0, 95% CI 1.1 to 3.9; P=0.033). By

131   6 months this had risen to 44.4% and 29.3% respectively (RR 1.6, 95% CI 1.2 to 2.17;

132   P<0.001) and by 12 months to 46.6% and 32.8% respectively (RR 1.5, 95% CI 1.2 to 2.0;

133   P=0.0015). The levonorgestrel intra-uterine system was the most commonly chosen LARC

134   by women in the intervention group at all time points. Differences between intervention and

135   control groups in mean QOL scores across all domains at 6 and 12 months were small.

136   **Conclusions**

137   A complex intervention combining family physician training on contraceptive effectiveness

138   counselling and rapid access to LARC insertion clinics resulted in greater LARC uptake and

139   has the potential to reduce unintended pregnancies.

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142 **INTRODUCTION**

143 International evidence shows that the increased use of long-acting reversible contraceptives

144 (LARCs), defined as intrauterine devices (IUDs) and contraceptive implants, can reduce

145 unintended pregnancy and abortion rates across all stages of a woman's reproductive life.[1-4]

146 LARCs are the most effective reversible methods of contraception with typical-use failure

147 rates for women of 0.05 to 0.8% in the first-year of use compared with 9% with the oral

148 contraceptive pill and 18% with male condoms.[5] LARCs are highly acceptable to women and

149 also have higher continuation rates than other less-effective forms of contraception.[6 7]

150 Despite this evidence, the prescription and use of LARCs remains low. In the UK LARC

151 prescription by FPs fell by 6% from 2014-2016.[8] In the United States, LARC uptake is

152 increasing, but is around 14%.[9] Australia has similarly low rates with national data from

153 2012-2013 reporting that only 11% of women were using a LARC (6.1% for IUDs and 4.9%

154 for implants).[10]

155 In the US-based Contraceptive CHOICE Project (CHOICE), a prospective cohort study of

156 9,526 women aged between 14-45,[11] provision of evidence-based information about all

157 reversible contraceptive options through structured counselling as well as free provision of

158 implants and intrauterine devices, led to a significant increase in the uptake of LARC

159 compared to national averages. This resulted in a 20-fold reduction in unplanned pregnancy

160 rates at three years of follow-up compared with contraceptive pill, patch or ring-users[3] and a

161 significant reduction in abortion rates compared with the regional and national rates.[12] A

162 subsequent randomized controlled trial, also undertaken in reproductive health clinics in the

163 US, trained health care providers in LARC counselling and insertion but maintained normal

164 costs to replicate real-life conditions. This study resulted in increased rates of counselling and

165 LARC uptake in the intervention arm and reduced pregnancy rates in women attending for

166 family planning consultations.[13]

167 These two studies, both undertaken in specialised clinic settings, demonstrated that

168 improving health care provider knowledge and skills, as well as addressing some of the

169 financial and service access barriers,[14] can impact women's uptake of LARC. However, in

170 many countries, including Australia, specialised reproductive health services are not widely

171 available and women rely on their family physician (FP) for contraceptive counselling and

172 provision. While the barriers to primary care provision of LARC have been well

173 documented,[4 14] no studies to our knowledge have tested interventions in this setting.

174 Consequently, this study sought to compare a complex intervention on the uptake of LARC

175 in the family medicine practice setting.

176

177 **MATERIALS AND METHODS**

178 **Trial Design and Oversight**

179 The ACCORd trial was set in metropolitan Melbourne, Australia with the FP as the unit of

180 randomisation. Approved by the Monash University Human Research Ethics Committee: CF

181 14/3990-2014002066 and CF 16/188-2016000080, and conforming to CONSORT

182 guidelines,[15] the study was conducted and reported with fidelity to the protocol described

183 elsewhere.[16] The conduct of the trial was periodically reviewed by an independent data safety

184 monitoring committee consisting of a statistician and two academic researchers (independent

185 from the ACCORd study) who monitored recruitment, trial outcomes and adverse events. The

186 authors vouch for the accuracy and completeness of the data presented.

187 **Trial Population and Recruitment Procedures**

188 FPs were eligible if they worked three or more sessions (half days) per week, were based at a

189 computerized practice and had reception staff who could assist with recruiting. FP

190 recruitment took place between May 2016 and January 2017, and all FPs who participated in

191   the study gave written consent at enrolment. To avoid contamination due to cross-over

192   effects, only one FP was included per practice. Participating FPs were accredited with

193   Continuing Professional Development points necessary to maintain professional FP

194   qualifications and received $500 (AUD) as reimbursement for time spent on completion of

195   the study.

196   Reception staff from ACCORd FPs invited women to complete an online eligibility survey

197   that included contact details using an iPad in the waiting room. Women were eligible to

198   participate if they were aged between 16-45, had been sexually active with a male partner in

199   the previous six months or anticipated sexual activity in the subsequent six months, had not

200   undergone tubal ligation or hysterectomy, had sexual partners who had not undergone a

201   vasectomy, were neither pregnant nor anticipating a pregnancy in the following 12 months,

202   spoke proficient English and were interested in discussing contraception or in starting a new,

203   reversible contraceptive method.

204   All eligible women were contacted by telephone by an ACCORd researcher to obtain consent

205   and complete baseline questionnaires. After enrolment, women were asked to return to their

206   ACCORd FP within one week for a contraceptive counselling appointment. Any additional

207   charges for this visit were covered by ACCORd to ensure that the women did not bear out-of-

208   pocket costs for this additional visit. ACCORd did not provide coverage for the cost of

209   individual contraceptive products.

210   **Randomisation and Masking**

211   The trial statistician generated a randomisation sequence with permuted blocks (block sizes

212   of 4, 6 and 8), stratified by whether the FP performed LARC insertion (IUDs/implants) or

213   not.[17] This sequence was then held by a research assistant who was not involved in the

214   ACCORD trial. When a FP was recruited, ACCORd staff contacted the research assistant to

215   assign the FP to the next allocation in the sequence.

216   **Interventions**

217   FPs in the intervention arm were trained to deliver structured contraceptive counselling and

218   given access to rapid referral to LARC insertion clinics through an online booking system.

219   Materials from the "LARC first" (contraceptive effectiveness) online training site of the

220   Contraceptive CHOICE project[3] were adapted to the Australian context with input from an

221   advisory group comprising the project investigators, FPs, and consumers. Training was

222   delivered online through a six-hour training package with additional practice visits, email,

223   and telephone support where required. Structured contraceptive counselling[18] consisting of

224   non-biased, scripted descriptions of all available contraceptive methods, with particular

225   reference to the safety and efficacy of each method, was then delivered to the participating

226   women by the intervention trained FPs. FPs also collected clinical information from the

227   women to identify any contraindications or conditions that may influence the choice of

228   contraception. Women were able to choose their contraception method provided that it was

229   not medically contraindicated. The FP was then advised to screen the woman for pregnancy

230   (history and urine pregnancy test) and chlamydia (according to clinical practice guidelines

231   published by the Royal Australian College of General Practitioners).[19] The online training

232   recommended ruling out pregnancy before: (a) providing a prescription for the method of

233   choice; (b) offering "same day" insertion of the LARC method, or at a subsequent time at the

234   FP clinic; or (c) providing an appointment for insertion of the LARC method at one of the

235   insertion clinics. Emergency contraception was advised for women who had recent

236   unprotected intercourse, while "quick start" contraception (i.e. commencing contraception at

237   any time rather than at the start of the next menstrual cycle) was recommended for women in

238   cases where pregnancy could be ruled out (as per the Faculty of Sexual and Reproductive

239   Healthcare guidelines).[20] In both of these cases a return appointment in three to four weeks

240   for a LARC insertion (and a repeat pregnancy test) was also recommended.

241   A rapid referral pathway to a LARC insertion clinic with two local private gynecologists was

242   implemented through an online booking system for intervention FPs who did not or chose not

243   to perform insertions in their own rooms. Gynecologists providing these LARC insertion

244   clinics received payment of $300 (AUD) per 3 ½ hour clinic undertaken and were free to

245   charge patients their usual fees at these clinics.

246   FPs in the control group provided usual contraceptive care to women recruited to this arm

247   and did not have access to the rapid referral LARC insertion clinics. At the conclusion of the

248   trial, the control group of FPs were invited to undertake the online contraceptive effectiveness

249   training.

250   Fidelity checking

251   To ensure fidelity of the counselling, a researcher (blinded to the allocation of the FP to

252   intervention or control arm) visited FPs in both groups. During this visit, the researcher

253   observed a single consultation and completed a checklist regarding the content of the

254   contraceptive counselling provided to ascertain whether the counselling was structured with

255   an emphasis on effectiveness.

256   Trial Measures

257   At baseline eligible women undertook an initial telephone based questionnaire drawn from

258   the US Contraceptive Choice Project[3] and including the Health Literacy Questionnaire

259   (HLQ),[21] and Medical Outcomes Survey (SF-36).[22] Further surveys were conducted online at

260   6 months (including the SF-36) and at 12 months (including the HLQ and SF-36). After

261   completing each survey women were given an entry into a monthly prize draw for a $150 gift

262   voucher.

263 Participating FPs and gynecologists working in the LARC insertion clinics were asked to

264 complete a standardised data collection form at every consultation involving an ACCORd

265 participant.

266 **Primary and secondary outcomes**

267 The primary outcome was the proportion of women who had a LARC inserted within 4

268 weeks of the initial contraceptive consultation with their FP. Secondary outcomes included

269 women's choice of contraceptive method, quality of life and LARC use at 6 and 12 months.

270 These outcomes were measured using data sourced from the standardised data collection

271 forms and from the 6 and 12 month surveys.

272 **Statistical analysis**

273 Current LARC use increased from 2.3% to 11% of all contraceptives use in Australia over a

274 13 year time frame.[10 23] A British study estimated that if 5% of British women who used oral

275 contraceptives used LARC instead, the decrease in contraceptive failure would result in 7,500

276 annual unplanned pregnancies.[24] Therefore, we chose an effect size of 10%. We estimated

277 that we would require 24 FPs and 24 women per FP in each of the two study arms

278 (intervention and control) to detect a 10% increase in the LARC insertion rate, with 80%

279 power and a significance level of 5% allowing for stratification according to whether or not

280 FPs inserted LARCs and a clustering effect (intracluster correlation (ICC)) of 0.05. This

281 corresponds to the maximum ICC for variables associated with FP–patient encounters in a

282 recent cluster RCT [25] and other FP-specific studies.[26] We aimed to recruit 27 FPs and 27

283 women per FP in each of the two study arms to allow for up to a 10% drop-out among FPs

284 and a 10% drop-out among women.

285 We calculated counts and proportions for descriptive characteristics of FPs and women at

286 baseline. We used the $\chi2$ test, adjusted for clustering and stratification by whether the FP

287   inserted LARCs, and binary regression models with generalized estimating equations and

288   robust standard errors, to compare the proportions of women who had a LARC inserted (the

289   primary outcome) between the intervention and control groups for women who had outcome

290   data available. The outcomes for women were analysed according to their randomized group

291   (intention-to-treat analysis). This method was also applied to the secondary outcomes of

292   LARC use at 6 and 12 months. Linear regression models also adjusting for study design were

293   used to compare mean QOL scores between groups. We conducted sensitivity analyses by

294   adjusting for the following variables: FP sex, FP age group, women's age group, parity and

295   use of LARC at baseline. Additional sensitivity analyses were carried out assuming that

296   women with missing outcome data were not missing at random. For these analyses, we used

297   multiple imputation under plausible missing data scenarios - women with missing outcome

298   data had (1) the same probability of the outcome as those from the same arm; (2) the same

299   probability of the outcome as those from the control arm; (3) the same probability of the

300   outcome as those from the intervention arm; (4) no LARC inserted. Twenty imputation

301   datasets were created in each analysis and the results were combined using Rubin's rules. In

302   the binary regression models we investigated whether the effect of the intervention varied

303   across subgroups defined by age, parity, use of LARC at baseline, marital status,

304   socioeconomic status, education, previous unintended pregnancy and previous abortion using

305   interaction terms. All analyses were carried out using SAS v9.4.

306   **Stakeholder involvement**

307   Prior to commencement of recruitment and prior to final ethics submission, the study tools

308   (FP surveys) were piloted among five FPs who provided suggestions for amendment. FPs

309   were also asked to assess the burden of intervention and the time required to participate in the

310   study.

311

312   **RESULTS**

313   **Trial Sites and Participants**

314   From April 2016 to May 2017, 43 FPs were randomly allocated to the intervention group

315   (with 25 subsequent withdrawals) and 44 to the control group (with 23 subsequent

316   withdrawals). A total of 25 intervention FPs recruited at least one participant, as did 32

317   control FPs (Figure 1). The characteristics of the FPs were well-balanced between the

318   intervention and control groups (Table 1). The majority of the FPs were females, aged 35 to

319   54 and inserted implants but not IUDs. Most FPs (81%) had 10 or more years of experience.

320   Recognised training in contraception had been undertaken by 25% of FPs, and 40% of

321   intervention FPs and 34% of control FPs also having specific training in IUD insertion (Table

322   1).

323   Between June 2016 and July 2017, intervention FPs recruited 410 women (103 women

324   initially expressed an interest in the study but did not consent) and control FPs recruited 622

325   women (189 women initially expressed an interest in the study but did not consent), resulting

326   in 307 and 433 women in the intervention and control arms respectively (N=740). The

327   characteristics of the women were also well-balanced between the two groups (Table 1). This

328   balance was retained among women with available data from the Standardised Data

329   Collection Forms and from the 6 and 12 month survey. Most women were aged under 35

330   years, had no children and were not currently using a LARC. The rate of cohort retention was

331   71% in both groups.

332

333 **Primary and Secondary Outcomes**

334 Within 4 weeks of the contraceptive counselling consultation 8% more women in the

335 intervention group than in the control group had had a LARC inserted (95% confidence

336 interval (CI), 1.5 to 15.4 P=0.018) (Table 2), with ICC of 0.13.

337 LARC uptake continued to rise with time at 6 and 12 months with a greater proportion of

338 women in the intervention group (44% and 47%, respectively) currently using a LARC

339 compared to the control group (29% and 33%, respectively) (Table 2).

340 The levonorgestrel IUS was the most commonly chosen LARC in the intervention group and

341 the etonogestrel implant in the control group at the 4 week, 6 month and 12 month time

342 points. (Table 3). None of the interaction tests indicated a differential effect of the

343 intervention across subgroups defined by age, parity, use of LARC at baseline, marital status,

344 socioeconomic status, education, previous unintended pregnancy or previous abortion

345 (Supplementary Table A1).

346 The results of the primary outcome analysis were similar, although the effects were smaller,

347 when covariates were adjusted for or when missing data were imputed under various

348 assumptions. The P-values for the comparison of binary outcomes were similar when

349 calculated using the $\chi 2$ test, adjusted for clustering and stratification or using binary

350 regression with GEE for all outcomes except for insertion at 4 weeks where the P-values

351 were 0.20 and 0.03, respectively (Supplementary Table A2).

352 The differences between intervention and control groups in mean QOL scores across all

353 domains at 6 and 12 months were small and unlikely to be of practical importance or clinical

354 significance despite two of the comparisons being statistically significant. The statistically

355 significant differences did not persist at 12 months (Table 4).

356

357   **Process Data**

358   Fidelity checks were completed for nine intervention FPs and 12 control FPs. Initiation of

359   structured efficacy-based contraceptive counselling was observed for 44% of the intervention

360   FPs (n=4) compared with 8% of the control FPs (n=1). Also, the data monitoring committee

361   met every three months during the recruitment and data collection phases of the study. No

362   unexpected complications nor adverse-effects were noted in either group.

363

364   **STRUCTURED DISCUSSION / COMMENT**

365   **Principal Findings**

366   The ACCORd trial results demonstrate that a family medicine practice based intervention

367   consisting of online training in structured effectiveness-based contraceptive counselling and

368   the provision of a rapid referral pathway to LARC insertion clinics results in increased LARC

369   uptake. Women participants of FPs who had received these interventions were significantly

370   more likely to have had a LARC inserted 4 weeks from receipt of contraceptive counselling

371   by their FP. This number increased by 6 months and increased further at 12 months.

372   **Results (in context of what is known)**

373   While ACCORd was modelled on the successful CHOICE study in the USA,[11] our

374   intervention differed from CHOICE in that it did not focus on reducing the cost of

375   contraceptive methods.   This suggests that in contexts such as Australia, where LARC

376   uptake is poor despite universal health coverage and subsidised contraception, the cost of

377   contraception for an individual woman may not impact on contraceptive decision-making as

378   much as receiving structured effectiveness-based contraceptive counselling and the

379   availability of a timely pathway to LARC insertion. Indeed the effect of the intervention did

380   not differ by socioeconomic status.

381   Lack of FP training in LARCs and LARC insertion has been identified as a barrier to

382   increasing LARC uptake.[14] Even with training, FPs often face difficulties sustaining practice

383   in LARC insertion, with one study finding that only about 30% of those trained in LARC

384   insertions continued to insert 12 or more devices per year, the minimum suggested by experts

385   to maintain skill levels.[27] The ACCORd intervention did not train FPs to insert LARCs.

386   Despite this it still achieved increased rates of LARC uptake. This may be because the

387   ACCORD intervention addressed other barriers that have been well described in the literature

388   such as tackling the myths and misconceptions concerning LARCs held by both FPs

389   (through the training) and women (through structured effectiveness focused counselling) and

390   by making LARC insertion more accessible through rapid referral pathways to insertion

391   clinics.

392   **Clinical Implications**

393   Our findings are important as ACCORd is the first trial to extend the efficacy demonstrated

394   by providing LARC education to doctors in reproductive health and family planning clinics[9]

395   to a new and important site - family practice. Extending LARC education to primary care

396   can assist the large number of women who access general practice for their health care. In

397   many countries internationally, there is a paucity of specialised contraceptive clinics, and

398   general practice is the main provider of women's sexual and reproductive health services,

399   particularly contraception.

400   **Research Implications**

401   While the trial demonstrated that a complex intervention involving training FPs to deliver

402   structured effectiveness-based contraceptive counselling and making available timely access

403   to LARC insertion clinics is effective at increasing LARC uptake, we cannot identify which

404   aspect of the intervention mattered the most. While LARC uptake increased in both

405   intervention and control groups the intervention group had higher uptake of the hormonal

406   IUS. This may indicate the importance of timely access to insertion clinics especially since

407   only 44% of intervention fidelity checks witnessed the delivery of structured efficacy based

408   contraceptive counselling.

409   **Strengths and Limitations**

410   The strengths of this study include the evaluation of the intervention in routine general

411   practices and examination of the sustainability of the effects after the availability of the

412   intervention had ceased. We undertook randomization of doctors rather than women in our

413   cluster randomized controlled trial. This reduced contamination which would have occurred

414   if women had been individually randomized, as individual women in the same practice may

415   have been in different arms of the study.

416   The intervention effect and the high cohort retention rate are also strengths providing us with

417   the opportunity to demonstrate the longevity of the effect of the ACCORd intervention.

418   While the use of LARCs in our population of women participants was lower at baseline

419   (13%) than a recently reported population based survey involving a younger population

420   (19%),[28] it was similar to another Australian study which reported 11% LARC use.[10] At six

421   months, 44% of our intervention group and 29% of our control group were using LARCs,

422   reflecting an increase in LARC use over both groups (but significantly higher in the

423   intervention group), and a higher proportion of current LARC users than recently reported. At

424   12 months the increase was sustained with 47% of women in the intervention group and 33%

425   in the control group. Longer follow up would have allowed us to determine if this rise in

426   LARC uptake persisted beyond one year.

427   Our trial had several limitations. Masking of doctors and women during implementation was

428   not feasible and because women's outcomes were self-reported there may have been some

429   bias responding to the survey questions.

430   Withdrawal of both FPs (58% in the intervention group and 52% in the control group) and

431   women participants (29% across both groups) from the study was higher than the 10%

432   anticipated. This may reflect the difficulty some FPs had completing a six-hour online

433   learning module, an inability of participants to spend the required time to complete the study,

434   and/or poor incentives for both FPs and women participants. Future research should focus on

435   determining whether other approaches to training FPs which are less time consuming such as

436   academic detailing or involvement in an online community of practice achieve the same

437   outcomes.

438   We originally designed the study with 24 FPs in each arm, and each FP recruiting 24 women.

439   However, once recruitment began it was apparent that some FPs would not reach the target of

440   24 women in the required time. For some FPs this was because their patient population did

441   not include many women of reproductive age. This was particularly the case for male FPs and

442   female FPs who were themselves over 45 years. To compensate we decided to recruit more

443   FPs, and we also allowed FPs (who were able) to recruit more than 24 women.

444   Setting one of the primary outcomes as LARC insertion at four weeks was problematic for

445   some women as there was a delay in returning to the FP for a contraceptive consultation, and

446   a further delay if LARC referral / insertion was instigated. A more clinically meaningful

447   outcome may have been LARC use at 6 months or 12 months, to reflect LARC insertion and

448   retention over time.

449   Our sample of FPs as well as their women patients were highly educated. We anticipated that

450   FPs interested in contraception would be over-represented in our study and indeed 25% of

451 ACCORd FPs had undertaken additional training in contraception. This rate was however

452 well balanced across both intervention and control groups, making the effect of our

453 intervention even more compelling. Non-inclusion of women who spoke limited English

454 may affect the generalizability of our findings to women of non-English speaking

455 backgrounds. Additionally, our sample of women was from the metropolitan area, and rural

456 women may face greater challenges with access to LARC insertion. The small number of

457 male FPs in our study may impact on the generalizability of the ACCORd intervention in

458 general practice settings where there are larger proportions of male practitioners.

459 The P-value for the outcome insertion at 4 weeks differed when calculated by the $\chi2$ test,

460 adjusted for clustering and stratification, and binary regression model with GEE. However,

461 the $\chi2$ test can be less powerful than binary regression and so may not detect a difference if it

462 exists and the binary regression model will provide an unbiased estimate with appropriate

463 confidence interval coverage. Hence, we consider the results from the binary regression

464 model to be more informative.[29 30]

465 **Conclusions**

466 In conclusion the provision of training to FPs in structured efficacy- focussed contraceptive

467 counselling together with providing FPs with a rapid referral pathway to LARC insertion

468 clinics results in increased LARC uptake. Implementation of this approach in family

469 medicine practice settings more broadly, particularly in contexts where free contraception is

470 not feasible, and specific sexual and reproductive health services are either not available or

471 accessible could lead to reductions in unplanned pregnancies and abortion.

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473

483   **Contributors**

484   DM, KB, AT, JL, KMG, MH, KM & JP contributed to the design of the trial. All authors

485   contributed to the development of the study tools, the interpretation of results and writing and

486   approval of the final paper. KMG advised on the design of the study, oversaw randomisation,

487   and undertook analyses.

494   **Ethics**

495   Approved by the Monash University Human Research Ethics Committee: CF 14/3990-

496   2014002066 and CF 16/188-2016000080

497

REFERENCES

498

499   1. Wellings K, Kyle G Jones, Mercer CH, et al. The prevalence of unplanned pregnancy and

500   associated factors in Britain: fi ndings from the third National Survey of Sexual

501   Attitudes and Lifestyles (Natsal-3). *Lancet* 2013;382:1807-16.

502   2. Taft AJ, Shanker M, Black KI, et al. Unintended and unwanted pregnancy in Australia: a

503   cross-sectional, national random telephone survey of prevalence and outcomes. *Med J*

504   *Aust* 2018;209(9):1-2.

505   3. Winner B, Peipert JF, Zhao Q, et al. Effectiveness of long-acting reversible contraception.

506   *N Engl J Med* 2012;366(21):1998-2007. doi: 10.1056/NEJMoa1110855

507   4. Gyllenberg FK, Saloranta TH, But A, et al. Induced abortion in a population entitled to

508   free-of-charge long-acting reversible contraception. *Obstet Gynecol* 2018;132:1453-

509   60. doi: 10.1097/AOG.0000000000002966

510   5. Sundaram A, Vaughan B, Kost K, et al. Contraceptive failure in the United States:

511   Estimates from the 2006-2010 National Survey of Family Growth. *Perspect Sex*

512   *Reprod Health* 2017;49(1):7-16. doi: 10.1363/psrh.12017

513   6. Diedrich JT, Desai S, Zhao Q, et al. Association of short-term bleeding and cramping

514   patterns with long-acting reversible contraceptive method satisfaction. *Am J Obstet*

515   *Gynecol* 2015;212(1):50.e1-50.e8.

516   7. Hubacher D, Spector H, Monteith C, et al. Long-acting reversible contraceptive

517   acceptability and unintended pregnancy among women presenting for short-acting

518   methods: a randomized patient preference trial. *Am J Obstet Gynecol* 2017

519   (February):101-09.

520   8. NHS Digital. Statistics on Sexual and Reproductive Health Services. England: 2016/17. In:

521   Service GS, ed. UK: *National Statistics*, 2017:1-27.

522   9. Kavanaugh ML, Jerman J. Original research article: Contraceptive method use in the

523   United States: trends and characteristics between 2008, 2012 and 2014. *Contraception*

524   2018;97(1):14-21. doi: 10.1016/j.contraception.2017.10.003

525   10. Richters J, Fitzadam S, Yeung A, et al. Contraceptive practices among women: the

526   second Australian study of health and relationships. *Contraception* 2016;94(5):548-

527   55. doi: 10.1016/j.contraception.2016.06.016

528   11. Secura GM, Allsworth JE, Madden T, et al. The Contraceptive CHOICE Project:

529   reducing barriers to long-acting reversible contraception. *Am J Obstet Gynecol*

530   2010;203(2):115 e1-7. doi: 10.1016/j.ajog.2010.04.017

531   12. Peipert JF, Zhao Q, Allsworth JE, et al. Continuation and satisfaction of reversible

532   contraception. *Obstet Gynecol* 2011;117(5):1105-13.

533   13. Harper CC, Rocca CH, Thompson KM, et al. Reductions in pregnancy rates in the USA

534   with long-acting reversible contraception: a cluster randomised trial. *Lancet*

535   2015;386(9993):562-68. doi: http://dx.doi.org/10.1016/S0140-6736(14)62460-0

536   [published Online First: 16th June 2015]

537   14. Mazza D, Bateson D, Frearson M, et al. Current barriers and potential strategies to

538   increase the use of long-acting reversible contraception (LARC) to reduce the rate of

539   unintended pregnancies in Australia: An expert roundtable discussion. *ANZJOG*

540   2017;57(2):206-12. doi: 10.1111/ajo.12587

541   15. Campbell MK, Elbourne DR, Altman DG, et al. CONSORT statement: extension to

542   cluster randomised trials. *BMJ* 2004;328(7441):702-8. doi:

543   10.1136/bmj.328.7441.702

544   16. Mazza D, Black K, Taft A, et al. Increasing the uptake of long-acting reversible

545   contraception in general practice: the Australian Contraceptive ChOice pRoject

546   (ACCORd) cluster randomised controlled trial protocol. *BMJ open* 2016;6:1-10. doi:

547   doi:10.1136/bmjopen-2016-012491

548   17. Piantadosi S. *Clinical Trials: a Methodologic Perspective*. 2nd ed. ed. NJ, USA: John

549   Wiley & Sons 2005.

550   18. Madden T, Mullersman JL, Omvig KJ, et al. Structured contraceptive counseling

551   provided by the Contraceptive CHOICE Project. *Contraception* 2013;88(2):243-9.

552   doi: 10.1016/j.contraception.2012.07.015

553   19. RACGP. Guidelines for Preventive Activities in General Practice 9th Edition. *East*

554   *Melbourne Australia: The Royal Australian College of General Practitioners*

555   2018;https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-

556   guidelines/view-all-racgp-guidelines/red-book

557   20. FSRH. Faculty of Sexual and Reproductive Healthcare *Clinical Guidance: Quick starting*

558   *contraception.* London, UK: Faculty of Sexual and Reproductive Healthcare, 2017.

559   21. Dodson S, Beauchamp A, Batterham RW, et al. Information sheet 10: *About the Health*

560   *Literacy Questionnaire (HLQ).* Ophelia Toolkit, 2014.

561   22. RAND. 36-Item Short Form Survey from the RAND Medical Outcomes Study

562   California, USA: RAND Health Corporation; 1994-2016 [Available from:

563   https://www.rand.org/health/surveys_tools/mos/mos_core_36item.html accessed

564   10/4/2019 2019.

565   23. Richters J, Grulich AE, de Visser RO, et al. Sex in Australia: contraceptive practices

566   among a representative sample of women. *Aust N Z J Public Health* 2003;27(2):210-

567   6.

568   24. Mavranezouli I, LARC Guideline Development Group. The cost-effectiveness of long-

569   acting reversible contraceptive methods in the UK: analysis based on a decision-

570   analytic model developed for a National Institute for Health and Clinical Excellence

571   (NICE) clinical practice guideline. *Hum Reprod* 2008;23(6):1338-45. doi:

572   10.1093/humrep/den091

573 25. Hegarty K, O'Doherty L, Taft A, et al. Screening and counselling in the primary care

574   setting for women who have experienced intimate partner violence (WEAVE): a

575   cluster randomised controlled trial. *Lancet* 2013;382(9888):249-58. doi:

576   10.1016/S0140-6736(13)60052-5

577 26. Britt H, Miller GC, Charles J, et al. BEACH: bettering the evaluation and care of health:

578   general practice activity in Australia 2005-06. *BEACH: bettering the evaluation and*

579   *care of health: general practice activity in Australia 2005-06* 2007(2007 Jan)

580 27. Stewart M, Digiusto E, Bateson D, et al. Outcomes of intrauterine device insertion

581   training for doctors working in primary care. *Aust Fam Physician* 2016(11):837.

582 28. Coombe J, Harris ML, Loxton D. Who uses long-acting reversible contraception? Profile

583   of LARC users in the CUPID cohort. *Sex Reprod Healthc* 2017;11:19-24. doi:

584   10.1016/j.srhc.2016.09.003

585 29. Austin PC. A comparison of the statistical power of different methods for the analysis of

586   cluster randomization trials with binary outcomes. *StatMed* 2007;26(19):3550-65.

587 30. Ukoumunne OC, Forbes AB, Carlin JB, et al. Comparison of the risk difference, risk ratio

588   and odds ratio scales for quantifying the unadjusted intervention effect in cluster

589   randomized trials. *Stat Med* 2008;27(25):5143-55.

590

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

599

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

601   † CI: Confidence intervals

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

603   § LARC: Long-acting reversible contraceptives

604

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)

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

606   § 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

607   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

608   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

609   differentiate between hormonal and copper intrauterine devices.

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

611   ¶ 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)	

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36
	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	No	219	179 (81.7)	40 (18.3)	333	33 (9.9)	300 (90.1)	0.82
LARC* at	Yes	29	8 (27.6)	21 (72.4)	45	12 (26.7)	33 (73.3)	
baseline								

*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

Figure 1: Trial flow chart

Table 1: Characteristics of family physicians and women participants

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

Table 3: Choice of contraceptive method

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

Supplementary Tables

Table A1: Subgroup analysis. Insertion of LARC at 4 weeks

Table A2: P-values from Chi-squared Mantel-Haenszel analysis (MHA) and binary

regression models with Generalized Estimating Equations (GEE) for outcomes

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