

ACCORd STUDY   
STATISTICAL ANALYSIS PLAN

ANALYSIS PLAN

* 1. OVERVIEW

The increased use of long-acting reversible contraceptives (LARCs), such as intrauterine devices and hormonal implants, has the potential to reduce unintended pregnancy and abortion rates. However, use of LARCs in Australia is very low, despite clinical practice guidance and statements by national and international peak bodies advocating their increased use. The Australian Contraceptive ChOice pRojet (ACCORd), is an NHMRC funded cluster randomised control trial that aims to test whether an educational intervention targeting general practitioners (GPs) and establishing a rapid referral service are a cost-effective means of increasing LARC

**Primary objective**

The ***primary objective*** is to evaluate whether the a complex intervention that involves training GPs to provide “LARC First” structured contraceptive counselling and implementing rapid referral pathways to LARC insertion will increase the uptake of LARCs.

**Secondary objectives**

The ***secondary objectives*** are to evaluate whether the complex intervention will:

* have an impact on choice of LARC;
* have an impact on LARC use at 6 months
* have an impact on LARC use at 12 months
* have an impact on quality of life at 12 months;
  1. RESEARCH QUESTIONS
     1. analysis 1

Primary research question

Does a complex intervention that involves training GPs to provide “LARC First” structured contraceptive counselling and implementing rapid referral pathways to LARC insertion increase the uptake of LARCs?

SECONDARY RESEARCH QUESTIONS

Secondary objectives

Does the complex intervention have an impact on the choice of LARCs?

Does the complex intervention have an impact on LARC use at 6 months?

Does the complex intervention have an impact on LARC use at 12 months?

Does the complex intervention have an impact on quality of life at 12 months?

Comparison with Contraceptive CHOICE Project (CHOICE) data [1].

EXPLORATORY RESEARCH QUESTIONS

**Quality of life**

How does the quality of life (QoL) compare for women using different forms of contraception?

Is the QoL better for women using LARCs?

**Economic evaluation**

How do the costs and outcomes of the intervention and control groups compare?

**Process evaluation**

Does the complex intervention provide an appropriate, workable and effective method of providing contraceptive counselling?

How did involvement in ACCORd impact practice of GPs?

Were women satisfied with contraceptive counselling provided by ACCORd GPs, and how does this compare with the experience of women in the control group?

**GP impact**

Did the complex intervention impact the knowledge, attitudes and practice of GPs participating in the ACCORd study?

What GP characteristics (e.g gender/ time as a GP /additional qualifications) and practice (e.g. size/ staff composition) are associated with LARC prescription?

**KAP survey**

Do the knowledge, attitudes and practice of GPs in metropolitan Melbourne reflect the RANZCOG position statement on LARCs?

**Condoms use**

What factors are associated with use of condoms?

Among women who use condoms and were sexually active in past 30 days, what factors were associated with consistent use of condoms (every time / almost every time) compared with inconsistent use?

What is the correlation with living situation/unintended pregnancies/length of time with current partner/number of sexual partners with condom use?

Who has the final say with condom use: women or their partners?

Do certain situations influence use of condoms?

How satisfied are women with use of condoms?

**Recruitment**

What lessons have been learned regarding recruiting and retaining GPs for complex trials?

What lessons have been learned for recruiting and retaining women participants for complex trials?

**Women’s contraceptive choices**

How does health / reproductive health influence women’s contraceptive choices?

What characteristics of women (socio-demographic/life stage etc) are associated with likelihood of recommending / prescribing LARC?

Conditional on a woman having previous experience of a LARC or conditional on a GP having recommended a LARC, what is the probability of a LARC being recommended or prescribed?

What is the continuation rate and satisfaction of reversible contraception for women? What characteristics are associated with discontinuation of LARCs within first six months? Is there an association with long-term bleeding / cramping patterns with LARCS? Comparison with Contraceptive CHOICE Project (CHOICE) data [1].

* 1. STUDY DESIGN

This is a cluster randomised controlled trial

* 1. STUDY POPULATION

Two study populations comprising:

1. General Practitioners (GPs) from metropolitan Melbourne
2. Women participants of the GPs
   * 1. INCLUSION CRITERIA

**General Practitioners**

* worked three or more sessions per week
* based at a computerised practice
* had a receptionist who could assist with the recruitment of women (patients of the GP)

To avoid contamination due to cross-over effects, only one GP per practice was included.

**Women**

* aged between 16 and 45 years
* sexually active with a male partner in the previous 6 months / anticipate sexual activity in the next 6 months
* no tubal ligation / hysterectomy
* partner(s) not had vasectomy
* not pregnant / planning a pregnancy in the following 12 months
* proficient English
* interested in discussing contraception / starting a new, reversible contraceptive method
  + 1. analysis

primary outcome

The primary outcome is whether a woman has had a LARC inserted following the contraception consultation with GP.

SECONDARY outcomes

M1. Choice of LARC following consultation

M2. LARC use at 6 months

M3. LARC use at 12 months

M4. Quality of life at 12 months measured using SF-36

exploratory outcomes

* 1. ethics & TRIAL REGISTRATION

The ACCORd study has been approved by the Monash University Human Research Ethics Committee: CF14/3990-2014002066 and CF16/188-2016000080. (project no. 11065). Trial registration number: ACTRN12615001346561.

* 1. dATA MANAGEMENT
     1. Data sources

Not applicable.

* + 1. data storage and security

All questionnaire data will be entered into a REDCAP database. The Study coordinator will run audits to check data entry.

**Data cleaning and database lock**

After the study has closed, data cleaning will be undertaken first by the data manager and then by the study statistician. This will include logic checks; examination of minimum, maximum values and frequency tables for out of range values; and percentage of missing values. All potential problems will be followed up with data queries. When there are no further data queries by the study statistician, the database will be locked. Access to data will be via a secure password protected network.

* 1. STATISTICAL ANALYSES
     1. SAMPLE SIZE

In our study, originally we aimed to have 24 GPs (in each arm) each recruiting 24 women; that is, GPs n=48, women 1,152. ACCORd aimed to recruit a total of 27 GPs and 27 women per GP in each of the two study arms to allow for up to a 10% drop-out among GPs and a 10% drop-out among women.

With these numbers, the study would have 90% power to detect a change from 10% to 20% in LARC insertion rates at the 5% significance level and an intra-cluster correlation (ICC) of 0.05. This power calculation also takes into account that we have stratified the randomisation by whether the GPs are LARC inserters themselves. Stratifying requires a larger sample size in a cluster RCT when the outcome is binary.



In the graph above stratification is not accounted for. Consequently, the power for a study with 24 GPs and 24 women per GP has the power at approximately 90% (the flesh coloured line). However, the graph provides a useful guide to assess what changes are expected when the number of GPs or women are changed.

The power drops from approximately 90% to just over 80% when the number of women per GP drops from 24 to 14. When the number of GPs in each arm drops from 24 to 18 we also see an approximately 10% drop in power. As a power drop of more than 10% (80% to 70% is sub-optimal, the minimum women for each of the 24 GPs in each arm is 14 (n=672).

* + 1. dependent, independent and confounding variables

table 1. analysis

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Research question** | **Dependent variable** | | | **Independent variable/s** | |  | **Confounders** | |  |
| Primary research question | Variable | Type | Variable | | Type | | | Variable | Type |
| Does a complex intervention that involves training GPs to provide “LARC First” structured contraceptive counselling and implementing rapid referral pathways to LARC insertion increase the uptake of LARCs? | LARC insertion following consultation (yes/no)  Percentage of LARCs inserted | Binary  Continuous | Group allocation (Intervention / control)  Age (<25, 25-34, 35+)  Marital status  Socioeconomic status  Past use of LARCs  Parity  Previous abotrions  Previous STIs | | Binary  Categorical  Categorical  Categorical  Binary  Binary  Binary  Binary | | |  |  |
| **Secondary research questions** | **Variable** | **Type** | **Variable** | | **Type** | | | **Variable** | **Type** |
|  | LARC at 6 months (yes/no)  Percentage of LARCs inserted | Binary  Continuous | Group allocation (Intervention / control)  Age (<25, 25-34, 35+)  Marital status  Socioeconomic status  Past use of LARCs  Parity  Previous abortions  Previous STIs | | Binary  Categorical  Categorical  Categorical  Binary  Binary  Binary  Binary | | |  |  |
|  | LARC at 12 months  Percentage of LARCs inserted | Binary  Continuous | Group allocation (Intervention / control)  Age (<25, 25-34, 35+)  Marital status  Socioeconomic status  Past use of LARCs  Parity  Previous abortions  Previous STIs | | Binary  Categorical  Categorical  Categorical  Binary  Binary  Binary | | |  |  |
|  | Quality of life at 12 months | Categorical | Group allocation (intervention / control) | | Binary | | |  |  |

* + 1. statistical methods

The analysis of data for this study will be based on the objectives and endpoints outlined in the study protocol. Analyses will be conducted on locked study data using SAS version 9.4 or higher.

**General principles**

a) All tests will be two-sided.

b) Statistical significance will be set at 0.05, unless specified.

c) All statistics will include appropriate measures of uncertainty: standard deviations for descriptive statistics (or inter-quartile range for skewed data); and standard errors or 95% confidence intervals for inferential statistics.

d) All means and medians will be formatted to one more decimal place than the measured value. SDs will be formatted to two more decimal places than the measured value. For example, if age is recorded in years (28 years), mean age will be reported to one decimal place (28.4 years) and the SD of age will be reported to two decimal places (4.52 years).Patient and general practice characteristics will be summarised using the mean and standard deviation for continuous data and counts and percentages for categorical/binary data. Skewed data will be summarised using the median and interquartile range.

primary analysis

analysis methods for primary outcomes

LARC insertion following consultation, the primary outcome, will be analysed using the χ2 test adjusted for clustering and stratification by whether or not the GP inserts LARCs. Binary regression models with generalised estimating equations and robust SEs, also adjusted for clustering and stratification factors, will additionally adjust for the GP and woman level covariates of GP age and sex, and woman’s age and parity. We will fit separate binary regression models to provide differences in proportions and ratio of proportions as per CONSORT recommendations.

analysis methods for secondary outcomes

M1. Among women who choose a LARC the proportion who opt for different forms (hormonal IUS, copper IUS, implant) will be compared between the groups using multinomial logistic models adjusted for clustering and stratification.

M2 and M3. As for the primary analysis, LARC use at each time point will be compared between groups using the χ2 test and binary regression models.

M4. Mean quality of life scores at 12 months will be compared using a linear mixed model adjusting for clustering by GP and stratification.

**Subgroup analysis**

Binary regression models analysing the primary outcome as a ratio of proportions will be used to assess whether there is an interaction between allocation group and any of the following covariates – Age group (<25, 25 – 34, 35 and older), Marital status, Socioeconomic status, Past use of LARCs,

**Multiple endpoints**

No adjustment for multiple endpoints will be used.

analysis methods for exploratory outcomes

**Economic evaluation**

The costs and outcomes of the intervention and control will be compared in a cost-effectiveness analysis.

• a trial-based analysis

• decision model to extrapolate future costs and benefits beyond the completion of the trial.

Direct costs

• costs of consultations with GPs and LARC insertion clinics

• costs of the contraceptive products, including their administration, where appropriate (MBS \ PBS)

Indirect costs

• travel time

• time away from work for women in relation to their contraceptive-specific consultations.

Outcomes:

Quality Adjusted Life Year (QALY) SF-36 to assess the cost / QALY gained.

• cost-savings due to avoided unwanted pregnancies

• mean estimates of costs will be used and confidence intervals will be generated by boot-strapping the data.

Results will be presented in terms of the incremental cost-effectiveness ratio as cost / QALY gained. The robustness and validity of the cost-effectiveness analysis will be explored using sensitivity analysis.

Model: A modelled analysis is required to take into account costs and outcomes beyond the period of the trial. As noted, the effects of some LARCs may extend out to 10 years, whereas the trial follow-up is only 12 months. An estimate of the longer-term effects of the proposed intervention will be formed by modelling the longer term outcomes and costs associated with the use of SARC or LARC. This will be informed by the outcomes and resource use observed during the trial, and extrapolated using data from the literature with respect to what can be expected from longer term outcomes in terms of discontinuations in contraceptive use, pregnancy rates, the impact on quality of life and the use of medical/pharmaceutical resource use.

**Process evaluation**

The Realistic Evaluation model [2] to understand “what works for whom in what circumstances” will be used. This evaluative framework examines context, mechanism, and outcomes and consists of:

• GPs in the intervention arm completing a pre-evaluation knowledge, attitudes, and practices (KAP) survey as part of the training program and a post-evaluation KAP survey to be administered during the interview at 12 months

• GPs in the intervention arm completing short encounter forms describing the outcomes of the structured contraceptive counselling

• Semi-structured phone interviews with up to 20 women participants (sampled for maximum diversity in age, parity, and socioeconomic status) from each arm of the trial after the 12 month assessment to assess their experiences of receiving the intervention or usual care and perceived outcomes. The data collected includes satisfaction with counselling sessions / usual care, extent to which expectations of the counselling sessions / usual care were met, changes to usual GP care, quality of relationship with GP, experiences of being in the project, relationship with research team, and any changes women made in their relationships as a result of being involved in this study.

• Semi-structured phone interviews with all GPs from each arm of the trial to assess their perceptions of the research and intervention process and the impact on their practice, both positive and negative. The data collected will include satisfaction with training and counselling process / usual care, perceived impact of counselling / usual care on women, whether expectations of being involved in this study were met, and the perceived impact on their practice and sustainability of skills and practice.

Data from all sources, including the 6 and 12 month participant surveys, will be combined to understand what works for whom in what circumstances.

**GP Impact**

XXX will be used to determine whether the complex intervention impacted the knowledge, attitudes and practice of GPs participating in the ACCORd study, examining data from the baseline and 12 month KAP survey.

**KAP survey**

Descriptive statistics will be used to examine whether the knowledge, attitudes and practice of GPs in metropolitan Melbourne reflect the RANZCOG position statement on LARCs

**Condoms use**

Descriptive statistics will be used to detail contraception use in the ACCORd study and dual use of condoms with other forms of contraception.

Logistic regression will be used to determine factors that most predict current condom use and consistent condom use

**Recruitment**

Descriptive statistics will be used to detail recruitment of GPs, using means / standard deviations of GPs in both intervention and control groups, including:

* length of time from initial contact to enrolment
* length of time from enrolment for ALM completion
* number of points of contact required for each GP
* estimation of time required for recruitment of each GP

Factors included in withdrawal will also be examined, including:

* length of time from first contact to withdrawal
* reasons for withdrawal

**Women’s contraceptive choices**

Chi2 analysis will be used to determine associations with

* health / reproductive health and women’s contraceptive choices (including previous abortions)
* characteristics of women (socio-demographic/life stage etc) are associated with likelihood of recommending / prescribing LARC
* previous LARC and likelihood of GP recommending LARC
* long-term bleeding / cramping patterns with LARCs

XXX will be used to examine the continuation rate and satisfaction of reversible contraception for women

* + 1. sensitivity analyses and treatment of missing data

Sensitivity analyses will be performed to account for any woman who does not have the primary outcome recorded. For women who do not have a SCDF record following the contraception consult the responses at 6 and 12 months will be used to infer LARC uptake following the consultation. For women for whom there are no follow-up data available missing data will be imputed under different plausible scenarios – 1. women have the same probability of having a LARC inserted as similar women in the same group, 2. women have the same probability of having a LARC inserted as similar women in the control group, 3. women with missing data are assumed not to have had a LARC inserted. Multiple imputed datasets will be created under each scenario and analysed to determine whether the different missing patterns affect conclusions. Covariates considered to be associated with the outcome or with missingness will be included in the imputation model Missing data will be assumed to be missing at random. .

* + 1. definitions

**Questionnaires and their scoring**

SF-36 scored according to manual.

**Derived variables**

LARC inserted following contraceptive consultation will be derived from the Standardised Data Collection Forms (SDCF) completed by the GP. The SDCF at and immediately after the contraceptive consultation will be used to determine whether a LARC was inserted. Where a SDCF is not available, data will be retrieved from the women participant’s 6 month survey.

* + 1. analysis sets

**Intention to treat population**

All GPs and women will be analysed according to the group they were randomised.

* 1. presentation of results

table 1. demographics and practice characteristics of gps by allocation

|  |  |  |  |
| --- | --- | --- | --- |
| **GP / practice characteristic** | **Intervention n(%)** | **Control n(%)** | **Missing** |
| GP gender |  |  |  |
| Male |  |  |  |
| Female |  |  |  |
| Age (years) |  |  |  |
| <25 |  |  |  |
| 25-34 |  |  |  |
| 35+ |  |  |  |
| **Years worked in general practice** |  |  |  |
| <5 |  |  |  |
| 5-10 |  |  |  |
| 10+ |  |  |  |
| Country of birth |  |  |  |
| Australia |  |  |  |
| Other |  |  |  |
| Language spoken at home |  |  |  |
| English |  |  |  |
| Other |  |  |  |
| Qualifications |  |  |  |
| MBBS |  |  |  |
| GP registrar |  |  |  |
| FRACGP |  |  |  |
| DRANZCOG or equivalent |  |  |  |
| Family planning certificate or equivalent |  |  |  |
| Overseas trained |  |  |  |
| Bulk billing practice |  |  |  |
| Yes |  |  |  |
| No |  |  |  |
| **Which patients are bulk-billed?** |  |  |  |
| All |  |  |  |
| Health care card holders |  |  |  |
| Students |  |  |  |
| Pensioners |  |  |  |
| Children |  |  |  |
| **Accredited practice?** |  |  |  |
| Yes |  |  |  |
| No |  |  |  |
| **Practice size** |  |  |  |
| Small <xGPs) |  |  |  |
| Medium (x-y GPs) |  |  |  |
| Large (z+ GPs) |  |  |  |
| **Number of practice nurses per practice** |  |  |  |
| *Mean (SD)* |  |  |  |
| **If nurse employed., do they deliver women’s health?** |  |  |  |
| Yes |  |  |  |
| No |  |  |  |
| **If nurse employed, do they assist with surgical procedures?** |  |  |  |
| Yes |  |  |  |
| No |  |  |  |
| **How many hours of direct patient care hours worked each week** |  |  |  |
| <12 |  |  |  |
| 13-20 |  |  |  |
| 21+ |  |  |  |
| **Consultation in languages other than English?** |  |  |  |
| Yes |  |  |  |
| No |  |  |  |
| **Training in IUD insertion** |  |  |  |
| Yes |  |  |  |
| No |  |  |  |
| **Routine insertion of Implanon?** |  |  |  |
| Yes |  |  |  |
| No |  |  |  |
| **Numbers of Implanon inserted** |  |  |  |
| 1-5 per month |  |  |  |
| 6-10 per month |  |  |  |
| 10+ per month |  |  |  |
| **Others in practice insert Implanon?** |  |  |  |
| Yes |  |  |  |
| No |  |  |  |
| **Routine IUD insertion** |  |  |  |
| Yes |  |  |  |
| No |  |  |  |
| **Numbers if IUDs each month** |  |  |  |
| 1-5 |  |  |  |
| 6-10 |  |  |  |
| 10+ |  |  |  |
| **Anyone else in practice inserts IUDs?** |  |  |  |
| Yes |  |  |  |
| No |  |  |  |

Comment: there is too much detail in this table (and the following tables). Suggest initially completing table then combining some variables and omitting others so that it is smaller and more meaningful.

table 2. demographics of women by allocation

|  |  |  |  |
| --- | --- | --- | --- |
| **Patient Characteristic** | **Intervention n(%)** | **Control n(%)** | **Missing** |
| Age (years) |  |  |  |
| <25 |  |  |  |
| 25-34 |  |  |  |
| 35+ |  |  |  |
| Country of birth |  |  |  |
| Australia |  |  |  |
| Other |  |  |  |
| Indigenous status |  |  |  |
| Aboriginal / Torres Strait Islander |  |  |  |
| Language spoken at home |  |  |  |
| English |  |  |  |
| Other |  |  |  |
| Marital status |  |  |  |
| Married / defacto |  |  |  |
| Not married |  |  |  |
| **Highest level of education** |  |  |  |
| Year 11 or below |  |  |  |
| Cert 111 / 1V of Year 12 |  |  |  |
| Bachelor degree |  |  |  |
| Graduate diploma / certificate |  |  |  |
| Advanced diploma / certificate |  |  |  |
| Postgraduate degree |  |  |  |
| **Family of origin** |  |  |  |
| Parents |  |  |  |
| Guardians |  |  |  |
| Both |  |  |  |
| **Current living situation** |  |  |  |
| Parent / guardian |  |  |  |
| Sexual partner / spouse |  |  |  |
| Another relative |  |  |  |
| With own children |  |  |  |
| Friend / roommate |  |  |  |
| Alone |  |  |  |
| Shelter / group home / foster care |  |  |  |
| Homeless |  |  |  |
| Other |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Current work situation** |  |  |  |
| Working full-time (30+hrs/week) |  |  |  |
| Working part-time (<30 hrs/week) |  |  |  |
| Unemployed |  |  |  |
| Disabled / sick leave |  |  |  |
| Retired |  |  |  |
| Home-maker |  |  |  |
| Full-time student |  |  |  |
| Other |  |  |  |
| Index of relative socio-economic disadvantage (quartiles)  (including income, post-code) |  |  |  |
| 4 (least disadvantaged) |  |  |  |
| 3 |  |  |  |
| 2 |  |  |  |
| 1 (most disadvantaged) |  |  |  |
| **Household income** |  |  |  |
| <50 K per annum |  |  |  |
| 50-100 K per annum |  |  |  |
| >100 K per annum |  |  |  |
| Don’t know / refused |  |  |  |
| Number supported by this income |  |  |  |
| 0-3 |  |  |  |
| 4-6 |  |  |  |
| 7+ |  |  |  |
| Centrelink benefits |  |  |  |
| Yes |  |  |  |
| No |  |  |  |
| Refused |  |  |  |
| Health care card |  |  |  |
| Yes |  |  |  |
| No |  |  |  |
| Refused |  |  |  |
| Other pensions / unemployment benefits |  |  |  |
| Yes |  |  |  |
| No |  |  |  |
| Refused |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Difficulty paying for transport, housing, medical care or food in past 12 months |  |  |  |
| Yes |  |  |  |
| No |  |  |  |
| Refused |  |  |  |
| **Medical insurance** |  |  |  |
| Medicare only |  |  |  |
| Private health insurance |  |  |  |
| Disability insurance |  |  |  |
| Refused |  |  |  |
| Don’t know |  |  |  |
| Highest level of education mother/ female guardian completed |  |  |  |
| Postgraduate degree |  |  |  |
| Graduate diploma / certificate |  |  |  |
| Bachelor degree |  |  |  |
| Advanced Diploma / diploma |  |  |  |
| Cert 111 / 1V or Year 12 |  |  |  |
| Year 11 or below |  |  |  |
| No mother / female guardian |  |  |  |
| Don’t know |  |  |  |
| Highest level of education father / male guardian completed |  |  |  |
| Postgraduate degree |  |  |  |
| Graduate diploma / certificate |  |  |  |
| Bachelor degree |  |  |  |
| Advanced Diploma / diploma |  |  |  |
| Cert 111 / 1V or Year 12 |  |  |  |
| Year 11 or below |  |  |  |
| No mother / female guardian |  |  |  |
| Don’t know |  |  |  |
| Withdrawals |  |  |  |
| Withdrawn before baseline survey |  |  |  |
| Withdrawn before 6 month survey |  |  |  |
| Withdrawn before 12 month survey |  |  |  |
| Total withdrawn |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **General Practice Characteristics** |  | **n (%)** | **Missing n(%)** |
| Practice size |  |  |  |
| Small (<x GPs) |  |  |  |
| Medium (x-y GPs) |  |  |  |
| Large (>y GPs) |  |  |  |
| Number of doctors per practice, *mean (SD)* |  |  |  |
| Number of practice nurses per practice, *mean (SD)* |  |  |  |

analysis

table 3: larc uptake (primary research question)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | LARC inserted | No LARC inserted | % LARC inserted | Ratio (95% CI) | Difference (95% CI) | P-value | Adjusted results |  |
| Following initial contraceptive consultation |  |  |  |  |  |  |  |  |
| Intervention group |  |  |  |  |  |  |  |  |
| Control group |  |  |  |  |  |  |  |  |
| **At 6 months** |  |  |  |  |  |  |  |  |
| Intervention group |  |  |  |  |  |  |  |  |
| Control group |  |  |  |  |  |  |  |  |
| **At 12 months** |  |  |  |  |  |  |  |  |
| Intervention group |  |  |  |  |  |  |  |  |
| Control group |  |  |  |  |  |  |  |  |

table 4: larc uptake by sub-groups

larc inserted

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Intervention Group |  |  | Control group |  |  |  |  |
|  | Yes | No | % LARC inserted | Yes | No | % LARC inserted | Ratio (95% CI) | P-value for interaction |
| Age |  |  |  |  |  |  |  |  |
| <25 |  |  |  |  |  |  |  |  |
| 25-34 |  |  |  |  |  |  |  |  |
| 35+ |  |  |  |  |  |  |  |  |
| **Marital status** |  |  |  |  |  |  |  |  |
| Not married |  |  |  |  |  |  |  |  |
| Married / defacto |  |  |  |  |  |  |  |  |
| Country of birth |  |  |  |  |  |  |  |  |
| Australia |  |  |  |  |  |  |  |  |
| Other |  |  |  |  |  |  |  |  |
| Index of relative socio-economic disadvantage (quartiles)  (including income, post-code) |  |  |  |  |  |  |  |  |
| 4 (least disadvantaged) |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |
| 1 (most disadvantaged) |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medical insurance** |  |  |  |  |  |  |  |  |
| Medicare only |  |  |  |  |  |  |  |  |
| Private health insurance |  |  |  |  |  |  |  |  |
| Disability insurance |  |  |  |  |  |  |  |  |
| Refused |  |  |  |  |  |  |  |  |
| Don’t know |  |  |  |  |  |  |  |  |
| **Past use of LARCs** |  |  |  |  |  |  |  |  |
| Yes |  |  |  |  |  |  |  |  |
| No |  |  |  |  |  |  |  |  |
| **Parity** |  |  |  |  |  |  |  |  |
| Nulliparous |  |  |  |  |  |  |  |  |
| Multiparous |  |  |  |  |  |  |  |  |

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