

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Increasing the uptake of long-acting reversible contraception in general practice: The Australian Contraceptive ChOice pRoject (ACCORd) cluster randomised controlled trial protocol
AUTHORS	Mazza, Danielle; Black, Kirsten; Taft, Angela; Lucke, Jayne; McGeechan, Kevin; Haas, Marion; McKay, Heather; Peipert, Jeffery

VERSION 1 - REVIEW

REVIEWER	Anna Glasier University of Edinburgh Scotland
REVIEW RETURNED	20-May-2016

GENERAL COMMENTS	<p>Some points need a little bit of tidying.</p> <ol style="list-style-type: none"> 1. In the section entitled Study Design the authors state that The intervention arm will include GPs who have been trained to deliver LARC first counselling AND have rapid referral access to LARC insertion. The authors state that randomisation will be stratified by whether the GP inserts LARCs or not. However elsewhere in the methods section it is clear that not all GPs do have access to rapid referral for LARC insertion and that this will be arranged. Which is correct? This aspect of the study (which is surely vital to its success) must be clear. I think we need an estimate of how many GPs will insert LARC themselves (both IUDs and implants) and the exact arrangements for rapid access to insertion. This needs to be made clear in the abstract. 2. The authors admit in the section on limitations that they are not training GPs to insert LARC. There is ample data from a variety of sources that if women have to wait for their LARC insertion then a significant proportion never get the method. It will be vital that the source of LARC insertion (GP or referral) and the timing of the insertion (i.e. same day, within 5 days or longer) are recorded since this is likely to be a major determinant of uptake. 3. The protocol states that 'To ensure fidelity of the counselling, within 4 weeks of recruitment to the trial, random visits to all GPs will be conducted. During this visit, a researcher (blinded to the allocation of the GP to intervention or control arm) will be present at a single consultation. Using a checklist, the observer will assess whether GP participants in the intervention arm of the ACCORd project are delivering LARC-First structured counselling with the intent that was envisioned by the ACCORd team.' Surely as soon as the GP starts the consultation it will become clear whether or not they are giving the 'LARC first' message. How is the blinded researcher going to feed back the information to the research team? If the feedback is
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	<p>that the process is not being followed then might this be because the GP is in the control arm. The allocation will need then to be unblinded and what action will be taken if the GP is in the intervention arm but not performing appropriately. this aspect of the protocol is unclear.</p> <p>4. While the primary outcome is clear and pertinent I find the plan to measure QOL somewhat contrived. Is this simply to allow a cost-effectiveness analysis. Surely the most important long term outcome is continuation rates of the chosen method yet this is not mentioned in the proposal. Please justify the reason for measuring QOL.</p> <p>5. What is a Health Literacy Questionnaires and why is it being administered.</p> <p>6. The introduction cites a number of studies from the UK and USA. Method use and its determinants vary greatly from country to country. How relevant are the data from these other countries?</p>
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REVIEWER	Wendy V. Norman University of British Columbia, Canada
REVIEW RETURNED	02-Jun-2016

GENERAL COMMENTS	<p>2016 Jun 1 BMJO Review Comments to the Authors</p> <p>This is a well written paper detailing the protocol for a cluster RCT to determine the effect of a specific GP-delivered counselling approach on the uptake of highly effective contraceptives (LARC methods). General comments: The authors have adhered to CONSORT guidelines and include a CONSORT Checklist and flow chart. The trial has been registered, ethically approved and all appropriate declarations are made. The process for recruitment and randomization is clear and appropriate, including their plan to stratify based on current related skills among GPs.</p> <p>The introduction is compelling, however it is much longer than typical, and the references chosen appear particularly dated. The topic and evidence is rapidly accumulating to support the assertions claimed, yet in many cases references 10 and even 20 years old are cited even when more recent and comprehensive evidence is available.</p> <p>It is interesting that the research question asks whether educating GPs to conduct an intervention will have an effect on LARC uptake. However, in fact I think the protocol is testing whether the intervention itself will be effective. Although subtle, I believe this difference is important when estimating scalability and the overall health systems and health services implementation implications. For example, this protocol not only trains the GPs on how to do an intervention (not an uncommon factor in the health system-training in new interventions occurs all the time). The protocol goes on to include monitoring to ensure the GPs are delivering the rigidly defined intervention up to a high standard of replication (to ensure fidelity of the counselling), and includes mechanisms to demonstrate that they do so. How will this relate to real life? In what sense would an initial training of (for example) Australian GPs from a wide range of communities undertaken in the future scale up, relate to their ongoing delivery and eventual results. To be blunt, will the results of</p>
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this protocol have relevance to expected results in a real world large scale intervention? Is so, how will the research team estimate this delta?

In fact, this protocol is not testing the research question proposed, it is a test of whether GP delivery of a set intervention will have an effect on LARC uptake. The question of external validity and generalizability is not addressed. My suggestion is that a protocol to test the research question stated (will an educational intervention targeting GPs and establishing fast-track referral process are a cost-effective means of increasing the uptake...) would require that the monitoring of GP delivery after they have received the intervention be dropped. (Evidence suggests that the act of measuring their delivery will affect the nature of their output.) In a way, an “intention to treat” perspective on the education of the GPs will give a more realistic idea of the scalable effectiveness of the intervention. It is difficult to understand the potential pool of GPs in the target community (one chart suggests there may be 600) and how this number relates to the number of independent practices operating in the one community, could it really be over 50? And if so, what proportion of all practices would need to be enrolled in order that the target number of independent practices is achieved? In short is the recruitment goal feasible?

I am wondering as well about the medical ethics to have a research team observer present “at a... consultation”. Presumably these consultations are taking place within the delivery of health care by the Australian health care system and paid for by the Australian government as health care? Or is the study team paying for the initial and follow up consultations related to this care? Are all participating women consenting to an observed consultation? Similarly, it appears women are recruited when presenting at their GPs office for an appointment, but the recruitment and arrangement for an appointment to address their contraceptive care appears to be planned for some future date- not during the consultation at which they first hear of the study. What if this index GP consult had been planned by the woman to discuss contraception, and/or what if the GP would naturally have discussed contraception, at this visit prior to enrollment by phone with a researcher sometime later? I would like to see a clear explanation of the feasibility of recruitment for women using this protocol. Has it been tested, has a pilot of even ten women been attempted?

Why is there an hourly payment rate for LARC insertion clinic doctors, but not for the GPs inserting LARC in their own offices? Or, is the study paying for consultations and insertions uniformly? Does not the Australian health system compensate a doctor who would provide LARC insertions with a per-visit fee? How scalable would this approach be- is it analogous to other current approaches within the Australian health care system?

Similarly, as the project carries the same name as the highly successful US intervention, to what extent do the investigators estimate that GPs in general, and those in the control arm in particular, are or will become aware of the findings and implications of a “CHOICE Project” LARC first approach, and would be tending over the course of the study to implement these best practices? (thereby reducing your estimated effect size by increasing overall LARC uptake).

The intended analysis appears appropriate, although I am not qualified to comment on the cost-effectiveness analysis. The standard dissemination of results are mentioned, but I was surprised to see that planned discussions with residency training programs and national clinical practice guidelines were not

	<p>considered.</p> <p>Finally, although in a protocol paper a results section is pre-mature, I would expect to see a fulsome discussion of potential limitations of your study design, and any mitigation you can suggest.</p> <p>Specific comments:</p> <p>Introduction:</p> <p>Pg 3, Line 40, reference 1 is cited to support the first statement- yet none of the first three references are primary sources of information to derive this figure. Good primary sources are out there and should be cited.</p> <p>Pg 4, first sentence- poor grammar. "each method" (I don't think you intend to imply that the effectiveness of a given method varies widely, you wish to compare between them)</p> <p>Overall this is an important question and could be a great study, although perhaps ambitious. I very much look forward to the opportunity to review a revision.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Anna Glasier

Institution and Country: University of Edinburgh, Scotland

1. REVIEWER:

1. In the section entitled Study Design the authors state that 'The intervention arm will include GPs who have been trained to deliver LARC first counselling AND have rapid referral access to LARC insertion. The authors state that randomisation will be stratified by whether the GP inserts LARCs or not. However elsewhere in the methods section it is clear that not all GPs do have access to rapid referral for LARC insertion and that this will be arranged. Which is correct? This aspect of the study (which is surely vital to its success) must be clear.

RESPONSE: All GPs in the intervention group have access to the Rapid Referral Clinic (Page 11, Line 23)

Clarification inserted in the methods section page 11 line 17: "A rapid referral pathway to a LARC insertion clinic will be implemented for instances where the intervention group GP does not undertake insertions in their own rooms– GPs will book appointments for women to have a LARC insertion at study specific LARC insertion clinics provided in the rooms of local private gynaecologists... Doctors in the control group will perform their usual contraceptive care and will not have access to the rapid referral clinics."

REVIEWER: I think we need an estimate of how many GPs will insert LARC themselves (both IUDs and implants) and the exact arrangements for rapid access to insertion. This needs to be made clear in the abstract.

RESPONSE: There are no figures available for the proportion of GPs who insert IUDs in Australia. On page 7 line 25 it is stated: "Analysis of Australian general practice consultations using data from the Bettering the Evaluation and Care of Health (BEACH) program indicated that only 6.9% of all contraception consultations involved LARCs." For the purpose of this study we estimate the number of GPs who will insert IUDs would be 10% (since it is likely that those who are more interested in LARCs will respond to the study invitation). Adjustments will be made in analysis as necessary. Under "Sample size and calculation" (Page 13, line 33) is the statement: "The study requires 24 GPs and 24 women per GP in each of the two study arms (intervention and control) to detect a change in the LARC insertion rate from 10% to 20%,"

The abstract states that rapid referral pathways will be implemented. In the Methods section, this is explained: “GPs will book appointments from their rooms through an online booking system for women to have a LARC insertion at study specific LARC insertion clinics provided in the rooms of local private gynaecologists.” (Page 11 Line 19)

2. REVIEWER: The authors admit in the section on limitations that they are not training GPs to insert LARC. There is ample data from a variety of sources that if women have to wait for their LARC insertion then a significant proportion never get the method. It will be vital that the source of LARC insertion (GP or referral) and the timing of the insertion (i.e. same day, within 5 days or longer) are recorded since this is likely to be a major determinant of uptake.

RESPONSE: We agree with the reviewer’s suggestions. We will collect the source and timing of the LARC insertion. Addition on Page 12 line 25: Other data collected, such as time from consultation to insertion of LARC (see Figure 2) will be used to investigate mediating variables.

3. REVIEWER: The protocol states that ‘To ensure fidelity of the counselling, within 4 weeks of recruitment to the trial, random visits to all GPs will be conducted. During this visit, a researcher (blinded to the allocation of the GP to intervention or control arm) will be present at a single consultation. Using a checklist, the observer will assess whether GP participants in the intervention arm of the ACCORd project are delivering LARC-First structured counselling with the intent that was envisioned by the ACCORd team.’ Surely as soon as the GP starts the consultation it will become clear whether or not they are giving the ‘LARC first’ message. How is the blinded researcher going to feed back the information to the research team? If the feedback is that the process is not being followed then might this be because the GP is in the control arm. The allocation will need then to be unblinded and what action will be taken if the GP is in the intervention arm but not performing appropriately. this aspect of the protocol is unclear.

RESPONSE: The expectation is that more doctors in the intervention group will be providing ‘LARC first’ counselling for their patients than doctors in the control group as a direct result of the LARC First training and availability of rapid referral clinics. The blinded researcher will complete a checklist which will identify whether LARC first counselling is given, and will provide this to the ACCORd team, unaware of to which group the GP is allocated.

The fidelity check is part of the process evaluation which will assist in the evaluation of the results of the trial. The trial itself is evaluating whether the educational intervention we propose (together with the rapid referral pathway) actually impacts on practice and uptake of LARCs.

At Page 10, line 37 clarification to the manuscript as follows:

“During this visit, a researcher (blinded to the allocation of the GP to intervention or control arm) will observe a single consultation and complete a checklist. It is anticipated that a higher proportion of GPs in the intervention arm will deliver LARC-First structured counselling with the intent that was envisioned by the ACCORd team. This fidelity check will provide us with insights that will help explain the trial outcomes, that is, a change in LARC uptake.

4. REVIEWER: While the primary outcome is clear and pertinent I find the plan to measure QOL somewhat contrived. Is this simply to allow a cost-effectiveness analysis. Surely the most important long term outcome is continuation rates of the chosen method yet this is not mentioned in the proposal. Please justify the reason for measuring QOL.

RESPONSE: Evaluating the relative cost-effectiveness of the GP intervention is an integral aspect of the ACCORd study. While the use of LARC is likely to be cost-effective relative to, for example, the Pill, no economic evaluation has been undertaken of the cost-effectiveness of this GP education intervention as a means of increasing the uptake of LARC. The gold standard outcome in economic evaluations is the Quality Adjusted Life Year (QALY) which combines length and quality of life into

one measure which provides valuation of the health impacts on women. Such valuation is necessary so that the results of the cost-effectiveness analysis (i.e. cost/QALY gained) can be compared with that of proposed changes to practice and policy, both within and outside the sexual and reproductive arenas.

Each participant will complete a questionnaire at 12 months (Page 12 Line 20). Thus the continuation rate for each contraceptive method will be monitored over a 12 month period.

5. REVIEWER: What is a Health Literacy Questionnaires and why is it being administered.

RESPONSE: The Health Literacy Questionnaire is a validated tool designed to identify skills and knowledge which determine the motivation and ability of individuals to access healthcare and maintain good health. We will use it to compare demographic and behavioural characteristics of those who choose LARC over other methods of contraception.

Addition under Outcome evaluation (at page 12, line 3)

'We will also use the ...Health Literacy Questionnaire (HLQ) [42] which is a validated tool designed to identify skills and knowledge which determine the motivation and ability of individuals to access healthcare and maintain good health.'

6. REVIEWER: The introduction cites a number of studies from the UK and USA. Method use and its determinants vary greatly from country to country. How relevant are the data from these other countries?

RESPONSE: As there are limited data available on the uptake of LARCs in Australia, the data from other high income, comparable OECD countries are cited to give context and baseline data to this study, which is the first of its kind in Australia.

Reviewer: 2

Reviewer Name: Wendy V. Norman

Institution and Country: University of British Columbia, Canada

Competing Interests: None declared

REVIEWER: This is a well written paper detailing the protocol for a cluster RCT to determine the effect of a specific GP-delivered counselling approach on the uptake of highly effective contraceptives (LARC methods).

General comments:

The authors have adhered to CONSORT guidelines and include a CONSORT Checklist and flow chart. The trial has been registered, ethically approved and all appropriate declarations are made. The process for recruitment and randomization is clear and appropriate, including their plan to stratify based on current related skills among GPs.

The introduction is compelling, however it is much longer than typical, and the references chosen appear particularly dated. The topic and evidence is rapidly accumulating to support the assertions claimed, yet in many cases references 10 and even 20 years old are cited even when more recent and comprehensive evidence is available.

RESPONSE: Reference 17 (Forrest 1996) replaced with Alnakash & Abdulrazak 2008.

Reference 26 (Davie et al. 1996) replaced with Gretzer et al. 2013

A. REVIEWER

It is interesting that the research question asks whether educating GPs to conduct an intervention will have an effect on LARC uptake. However, in fact I think the protocol is testing whether the intervention itself will be effective. Although subtle, I believe this difference is important when estimating scalability and the overall health systems and health services implementation implications. For example, this protocol not only trains the GPs on how to do an intervention (not an uncommon factor in the health system—training in new interventions occurs all the time). The protocol goes on to include monitoring to ensure the GPs are delivering the rigidly defined intervention up to a high standard of replication (to ensure fidelity of the counselling), and includes mechanisms to demonstrate that they do so. How will this relate to real life?

RESPONSE: Our protocol includes a fidelity check for the purposes of a process evaluation ie to provide us with insights that will help explain the trial outcomes. It is not part of the intervention as in real life there would not be an opportunity for GPs to be monitored to assess the nature of the contraceptive counselling they are providing. The researchers are anticipating that the results will provide insights into the effectiveness of the intervention. One way of measuring the effectiveness of this intervention is whether it changes behaviour (i.e. contraceptive counselling) which then results in increased LARC uptake.

An addition to the manuscript at Page 10, line 37:

'This fidelity check will provide us with insights that will help explain the trial outcomes, that is, a change in LARC uptake.'

See also response to Reviewer 1 at point 3.

REVIEWER: In what sense would an initial training of (for example) Australian GPs from a wide range of communities undertaken in the future scale up, relate to their ongoing delivery and eventual results. To be blunt, will the results of this protocol have relevance to expected results in a real world large scale intervention?

Is so, how will the research team estimate this delta?

RESPONSE: There are no guarantees of the generalisability of this study as it is impossible to predict the characteristics of GPs who respond to the recruitment strategies. We will, however, be able to show whether the intervention can affect change, and most likely also to be able to comment on which GP characteristics are associated with change (e.g. age, gender, location, practice type).

Addition to manuscript in section Strengths and Limitations of study (page 3, line 22)

"The trial may provide insight into GP characteristics that are associated with change in practice following the educational intervention."

REVIEWER: In fact, this protocol is not testing the research question proposed, it is a test of whether GP delivery of a set intervention will have an effect on LARC uptake. The question of external validity and generalizability is not addressed. My suggestion is that a protocol to test the research question stated (will an educational intervention targeting GPs and establishing fast-track referral process are a cost-effective means of increasing the uptake...) would require that the monitoring of GP delivery after they have received the intervention be dropped. (Evidence suggests that the act of measuring their delivery will affect the nature of their output.) In a way, an "intention to treat" perspective on the education of the GPs will give a more realistic idea of the scalable effectiveness of the intervention.

RESPONSE: Without a fidelity check we would not be able to assess whether the educational intervention had resulted in a change in practice by the GPs to an effectiveness or LARC first approach. The aim of the fidelity check is to assess whether GP in the intervention group is following the contraceptive counselling LARC first methods as outlined in the educational intervention. This should result in a difference between the contraceptive counselling provided by the GPs in the intervention group compared with the control group. If the intervention, along with the rapid referral

clinic is effective in increasing the uptake of LARCs, then this could provide additional evidence to support advocating this practice on a national level.

B. REVIEWER:

It is difficult to understand the potential pool of GPs in the target community (one chart suggests there may be 600) and how this number relates to the number of independent practices operating in the one community, could it really be over 50?

And if so, what proportion of all practices would need to be enrolled in order that the target number of independent practices is achieved?

In short is the recruitment goal feasible?

RESPONSE: The reviewer is correct: the recruitment goal as stated was too ambitious. In the group of 606 GPs there are 93 individual practices. Since submitting this paper we have extended the catchment in order to achieve our recruitment goals. This change is reflected in Figure 1: Trial Flowchart.

C. REVIEWER:

I am wondering as well about the medical ethics to have a research team observer present “at a... consultation”. Presumably these consultations are taking place within the delivery of health care by the Australian health care system and paid for by the Australian government as health care? Or is the study team paying for the initial and follow up consultations related to this care?

RESPONSE: Ethics for the Fidelity Checks has been approved. The contraceptive counselling will be covered by Medicare, as is usual practice for contraceptive counselling. If the practice charges ‘out of pocket’ expenses to the patient, these will be covered by ACCORD.

REVIEWER: Are all participating women consenting to an observed consultation?

RESPONSE: Yes, all women are consenting to the observed consultation, although only one from each of 27 patients recruited by each GP will actually have the observed consultation.

REVIEWER: Similarly, it appears women are recruited when presenting at their GPs office for an appointment, but the recruitment and arrangement for an appointment to address their contraceptive care appears to be planned for some future date- not during the consultation at which they first hear of the study. What if this index GP consult had been planned by the woman to discuss contraception, and/or what if the GP would naturally have discussed contraception, at this visit prior to enrollment by phone with a researcher sometime later?

RESPONSE: If the woman is recruited following a contraceptive consult, the GP will conduct the consultation as usual, and fill in the Standardised Data Collection form (which will be discarded should the woman decide to not participate). She will be invited to participate in the study and if she agrees, will be a participant and undergo the usual; study protocol (consent, baseline questionnaires etc). If a LARC is to be inserted it will be according to the protocol determined by which group the GP is randomised (i.e. Rapid review clinic if the GP does not insert LARCs for the intervention GP, and usual insertion and referral practice for the control GP).

REVIEWER: I would like to see a clear explanation of the feasibility of recruitment for women using this protocol. Has it been tested, has a pilot of even ten women been attempted?

RESPONSE: No pilot of recruiting women for this study using this protocol has been attempted. However, we are confident this will be feasible. In a recent study, 596 women used touch-screens for surveys and 75% of them found it acceptable. Br J Gen Pract. 2013 Sep;63(614):e620-6. doi:

10.3399/bjgp13X671605. Access to chronic disease care in general practice: the acceptability of implementing systematic waiting-room screening using computer-based patient-reported risk status. Paul CL1, Carey M, Yoong SL, D'Este C, Makeham M, Henskens F.

D. REVIEWER:

Why is there an hourly payment rate for LARC insertion clinic doctors, but not for the GPs inserting LARC in their own offices? Or, is the study paying for consultations and insertions uniformly? Does not the Australian health system compensate a doctor who would provide LARC insertions with a per-visit fee? How scalable would this approach be- is it analogous to other current approaches within the Australian health care system?

RESPONSE: If GPs normally insert the LARCs in their own practices, they are not usually paid an extra fee for this, as it is usual practice. The LARC clinics are additional clinics set up by ACCORD and the Gynaecologists who are running these clinics are compensated \$300 per session. All GPs in this study are compensated \$500 for extra time spent on this study. Every GP in the Australian health system has the option to charge above the Medicare rebate, and this situation is no different, thus reflects the 'real-life' situation. The economic evaluation will assess the cost to the doctor, the patient and to the Australian healthcare system.

E. REVIEWER:

Similarly, as the project carries the same name as the highly successful US intervention, to what extent do the investigators estimate that GPs in general, and those in the control arm in particular, are or will become aware of the findings and implications of a "CHOICE Project" LARC first approach, and would be tending over the course of the study to implement these best practices? (thereby reducing your estimated effect size by increasing overall LARC uptake).

RESPONSE: Currently the uptake of LARCs in Australia, although slowly rising, is very low (recent figures from MBS give a 0.51 per 100 women have IUDs; figures for Implanon are not available). Thus far, the US-based CHOICE study appears to have had little significant impact on LARC insertion rates in Australia. Certainly, we will discuss the possible contamination effect from the CHOICE study in our findings.

F. REVIEWER:

The intended analysis appears appropriate, although I am not qualified to comment on the cost-effectiveness analysis.

G. REVIEWER:

The standard dissemination of results are mentioned, but I was surprised to see that planned discussions with residency training programs and national clinical practice guidelines were not considered.

RESPONSE: National guidelines already advocate LARC first, although change is slow at the clinical level. Planned discussions in residency training programs (should the outcome be in favour of the intervention having a significant result) is a welcome addition to dissemination options, and has been included in the paper. At Page 19, line 12:

'Discussions with residency training programs will also be undertaken.'

H. REVIEWER:

Finally, although in a protocol paper a results section is pre-mature, I would expect to see a fulsome discussion of potential limitations of your study design, and any mitigation you can suggest.

RESPONSE: Thank you for this suggestion. We added the following points to the limitations section

(page 3):

- We recognise that the participating GPs may not be representative of the Australian GP population: The trial is being conducted in a narrow setting focused on southeast Melbourne; and participating GPs who are interested in LARCs may be over-represented and the participating GPs may not be representative of the Australian GP population.
- The participating women may not be representative of women of reproductive age in Australia as women who do not speak English are excluded.

REVIEWER:

Specific comments:

Introduction:

Pg 3, Line 40, reference 1 is cited to support the first statement- yet none of the first three references are primary sources of information to derive this figure. Good primary sources are out there and should be cited.

RESPONSE: Reference 1 replaced with Sedgh G, Singh S, Hussain R: Intended and Unintended Pregnancies Worldwide in 2012 and Recent Trends. *Studies in Family Planning* 2014, 45(3):301-314.

REVIEWER:

Pg 4, first sentence- poor grammar. "each method" (I don't think you intend to imply that the effectiveness of a given method varies widely, you wish to compare between them)

RESPONSE: Sentence clarified: "While a number of safe contraceptive methods are currently available to women, the effectiveness of different each method in preventing pregnancy varies widely."

REVIEWER:

Overall this is an important question and could be a great study, although perhaps ambitious. I very much look forward to the opportunity to review a revision.

VERSION 2 – REVIEW

REVIEWER	Anna Glasier University of Edinburgh Scotland
REVIEW RETURNED	06-Aug-2016

GENERAL COMMENTS	<p>The authors have done a good job dealing with the comments from both reviewers. This is not going to be an easy study to do and it is pertinent that the sample size calculation is based on a fairly modest change in practice.</p> <p>Personally I believe that a large part of the explanation for the success of the OS Contraceptive CHOICE project lay with the fact that women were given their chosen method free of charge in a setting where all methods are expensive and so the cost benefits of using a method which lasts for years was pretty obvious. The fact that the effect of the Harper intervention was much more modest (and moreover, although rather unclear, the end point appeared to be selection of LARC and not actual uptake) speaks to the effect of providing the method free.</p> <p>I wish the authors luck with the study, we may all be considerably older before it is finished</p>
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REVIEWER	Wendy V. Norman University of British Columbia Vancouver, Canada
REVIEW RETURNED	21-Aug-2016

GENERAL COMMENTS	The authors have satisfactorily addressed all concerns that I had presented in the initial review.
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