Author’s response to reviews

Title: Illawarra Born cross generational health study: feasibility of a multi-generational birth cohort study

Authors:
Michelle Townsend (mtownsen@uow.edu.au)
Megan Kelly (meganj@uow.edu.au)
Pickard Judy (jpickard@uow.edu.au)
Theresa Larkin (tlarkin@uow.edu.au)
Victoria Flood (vicki.flood@sydney.edu.au)
Peter Caputi (pcaputi@uow.edu.au)
Ian Wright (iwright@uow.edu.au)
Alison Jones (alisonj@uow.edu.au)
Brin Grenyer (grenyer@uow.edu.au)

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Dear Andrew Hayen

Editor Pilot and Feasibility Studies

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Illawarra Born cross generational health study: feasibility of a multi-generational birth cohort study

Michelle L Townsend, PhD; Megan A Kelly; Pickard A Judy; Theresa A Larkin, PhD; Victoria M Flood, PhD; Peter Caputi, PhD; Ian M Wright; Alison Jones; Brin F.S. Grenyer, PhD

Pilot and Feasibility Studies
Thank you for the opportunity to respond to the peer reviewers. Please find below our response to each reviewer comment and an indication of how we have modified the manuscript.

Reviewer1: Comments to the Author

This is a very well written description of the pilot stage of a very interesting proposed multi-generational birth cohort study. It is important to publish pilot data and to raise awareness of the new cohort study. Cross-generational studies are rare, particularly those with a prospective design. I have minor comments as set out below.

RESPONSE FROM AUTHORS

Thank you for your positive feedback regarding this manuscript, we have responded to each point below.

REVIEWER 1 COMMENT

1. Are the characteristics of the participants in the pilot to be published elsewhere? Otherwise it would be interesting to include such information in this paper.

RESPONSE FROM AUTHORS

We are drafting this manuscript to report on our evaluation of the feasibility of the Illawarra Born cross generation health study. We view a feasibility article as outlined by O’Cathain et al. (2015) which describes a feasibility study as a study that addresses whether the planned study can be done. To this end we reported the data related to the participants that answers that question, but have not reported on the specific research findings. These are reported elsewhere and other studies on questions related to the pilot are forthcoming - with a focus on individual scientific questions. For example, there have been articles related to the findings of the study published as follows:


Additionally a systematic review was undertaken prior to the development of the feasibility study to inform the development:


Thus this paper represents an overall description of the pilot to establish feasibility and is an original study not under consideration elsewhere.

REVIEWER 1 COMMENT

2. I would like to see more information included about the main study. Are there primary or secondary endpoints for which the study is powered for instance? The plan is to recruit 1000 families. It is commendable that a bio-psycho-social framework is to be employed.
RESPONSE FROM AUTHORS

In response, we have added some further details about the main study as follows:

New text (line 156):

In the main study, recruitment will not be time limited, but continue until the target of 1000 pregnant women have been recruited. The main study of Illawarra Born could potentially include 1000 family units and have up to 7000 participants. The main study will allow for multiple births. Golding (Golding, 2009) argues that good statistical power can be obtained with birth cohort study sizes between 600 and 10,000 to obtain meaningful results.

REVIEWER 1 COMMENT

3. On page 8, elaborate on the issue of fluency in English.

RESPONSE FROM AUTHORS

The sentence has been changed to clarify as follows:

New text (line 187):

Inclusion and exclusion criteria: All pregnant women sufficiently fluent in English to be able to complete the surveys were eligible for recruitment, regardless of parity. No interpreter services were available to participants.

REVIEWER 1 COMMENT

4. Was the refusal rate recorded at the antenatal clinic stage?

RESPONSE FROM AUTHORS

Unfortunately refusal at the antenatal clinic stage was unable to be collected in a meaningful way.
5. In the pilot only the maternal grandmother was included, whereas in the main study, as I understand it, all grandparents will be included. Explain how this came about? It seems sensible at pilot stage to include only one grandparent.

RESPONSE FROM AUTHORS

Thank you for this comment. We agree for the pilot it is sensible to include only one grandparent. Maternal grandmothers were selected for convenience for the third generation. Pregnant women were our target participants, and they in turn were asked to pass on further information to their own mother. We have added this information to the manuscript as follows.

New text (line 243):

Maternal grandmothers were selected as representative of the third generation for convenience since their pregnant daughters were the initial consenting participants in the study.

6. I note that the challenges experienced are very similar to other studies and the key role of stakeholders, including health professionals.

RESPONSE FROM AUTHORS

Thank you for this comment. Our colleagues in health services are crucial in undertaking research of this kind. We underestimated the time required to obtain hospital approval to undertake the study, engage with management and then clinicians to build trust before commencing the study. Seeking involvement of clinicians in recruitment is a challenge when they feel over stretched. This was despite the research team having a number of clinicians that were based at the hospital.

7. Please proof the manuscript for minor typographical errors.
RESPONSE FROM AUTHORS

The manuscript has been thoroughly proofed and changes are tracked.

Reviewer: 2 Comments to the Author

The article type is provided as 'research' however the way that it has been written is in the format of a protocol and therefore does not have a results section and impacts on how informative the article is. The manuscript either needs to be re-written as a protocol, with no results or include results if written as a pilot study research article. This would be the preferred option. However, as a research article it would be expected to include pilot results both about the participants and the pilot metadata to inform the processes for the overall study i.e. duration of each of the visits, time to complete the questionnaires, assessments, biological samples etc; missing data.

RESPONSE FROM AUTHORS

Thank you for these suggestions. To clarify, the paper has been written as a feasibility pilot and we have made changes to the manuscript to respond to the reviewer’s comments. We now include metadata to inform the process for the overall study. These changes include duration of the visits, time to complete questionnaires and missing data. These changes have been made throughout the Method and Results section, which has been substantially rewritten following valuable feedback from the reviewer.

REVIEWER 2 COMMENT

Specific question about the Pilot study that are not clear - If there are 2500 births per year in the recruitment hospital, why did the recruitment period need to be so long (8 months) to contact 116 women and recruit 41 women to the study as it would be expected that 1600 births would occur in that period.
RESPONSE FROM AUTHORS

As this was a pilot we were not set up to recruit most of the women giving birth at the time, so we staggered recruitment as we solved various technical issues discussed. Midwives provided us with a small sample of women to contact to see if they would like further information about the study. Informal feedback from women who declined to participate was that the time commitments were demanding – two visits to the University facilities and the collection of cord blood at birth.

REVIEWER 2 COMMENT

Background

The background would benefit from having more structure and focus. Specifically stating why the larger study (Illawarra Born) is needed for which this pilot was conducted. Beginning the section on ease of recruitment rather than information gaps would strengthen the background.

RESPONSE FROM AUTHORS

The background section has been revised with the aim of providing more structure as suggested.

REVIEWER 2 COMMENT

The purpose of the pilot as stated line 150 is good, however, the article does not provide much information on the outcomes of the pilot study as promised in this statement.

RESPONSE FROM AUTHORS

Thank you for this comment. The article has been substantially revised to ensure the focus is as a feasibility pilot.
REVIEWER 2 COMMENT

The background section includes numerous statements that should be referenced such as the sentence at line 74, 75, 95, 97, 106, 109, 112, 113, 114, 218.162, 165.

RESPONSE FROM AUTHORS

Thank you for your feedback, citations have been added to all of these sentences as requested.

REVIEWER 2 COMMENT

Methods /Design

The methods section would benefit from the inclusion of a process diagram, for clarity and substantially reduce the amount of text. See an example from the French longitudinal study from birth at https://www.ined.fr/en/everything_about_population/demographic-facts-sheets/focus-on/French-longitudinal-study-from-birth-an-unprecedented-look-at-child-learning-in-the-first-year-of-elementary-school/. Also the existing two recruitment and outcome figures could easily be combined.

The methods section would also benefit from having sub headings as per the instructions to authors of:

* Aim, design and setting
* Sample frame and inclusion and exclusion criteria
* Recruitment and data collection timeline and processes
* Planned analysis and evaluation

The methods section should also be limited to methods so statement such as at line 256 are not required. What is required is factual information in what information is provided to the participants re their involvement in the study.
The statement at line 267 should be included as part of the design which includes that fact that health reports are not provided to the participants.

The resource information (line 273) if included should be part of the results section. Resources with regard to their impact on the conduct of overall study and how it informs the data collection etc need to be included in the conclusion and discussion.

The results of the exit online questionnaire (from line 284) should be in the results section.

The impact of the feedback on the overall study and how it informs the data collection etc needs to be included in the conclusion and Discussion.

RESPONSE FROM AUTHORS

- A data collection process and timeline diagram has now been included based on the reviewer’s suggestions. The existing two recruitment and outcome figures were deleted; information has been included in the new diagram (Figure 1).

- Subheadings have been added to the methods section as recommended.

- The content in the methods has been limited to methods and other content has been moved to the results to strengthen the intention of the study as a feasibility paper.
Results

A results section is required and should include sub headings that align with the purpose of the pilot study ie (i) Instrument finalisations (ii) determining statistical power for data collection (iii) evaluating the participant acceptability and (iii) evaluating recruitment and data collection processes.

As stated above I would have expected this section to include summaries of the data collected; examination of missing data; timings of visits; assessments etc as well as summaries of the feedback provided by participants and lessons learnt.

The discussion and conclusion section would then concentrate on how the main study will be modified based on the pilot.

RESPONSE FROM AUTHORS

We thank the reviewer for these helpful suggestions. A Results heading has been added along with the sub-heading Evaluating recruitment and data collection. We have now added summaries of the data collected; timings of visits; assessments have been included, however specific results of the participants has not been included as this is a feasibility paper. Therefore, the feedback from participants about the study has been included as the paper addresses participant acceptability and feasibility.
REVIEWER 2 COMMENT

Discussion

The discussion should not include any new information but rather a discussion of what is included in the methods and results. Therefore, the discussion regarding ethics approval and the delays is not appropriate without ethics approval being included in the methods and results (which should be the case). If you want to discuss partnership and staffing issues in the discussion information about what was done and what the results were need to be included in the appropriate sections.

The statement on p293 has not been demonstrated in the current manuscript.

The sampling bias (line 306) as the profile of the pilot participants is not provided. The burden on the participants and their extended family (from line 308) is also not provided (other than number of visits). I would have expected information on average times per visit, per task etc to be provided.

The information about the collection and processing of the biological samples (line 316 onwards) should have been included in the methods section and then just discussed in this section.

The discussion should include reference to other similar studies and how your finding may be of relevance to them and/or their issuers were similar.

RESPONSE FROM AUTHORS

We thank the reviewer for their comments and suggestions. The paper has been revised in light of the comments including re-ordering of the paper and ensuring sections are consistent. In addition, we have rewritten the discussion and conclusion, adding further citations and ensuring the content covered is also identified in the previous sections as suggested.
REVIEWER 2 COMMENT

Conclusion

How exactly did the findings assist in prioritising and finalising the hypotheses for the main study (statement beginning on line 340).

RESPONSE FROM AUTHORS

We agree this is an awkward sentence and it has now been removed. This section has been redrafted as follows.

Old text: Despite these challenges, the pilot study has demonstrated the acceptability of a cross-generation health study in the community, and enabled optimisation of recruitment, data collection time points and outcome measures. Furthermore, the findings have assisted in prioritising and finalising the hypotheses for the main study.

New text (Line 449)

The study established feasibility for a planned larger longitudinal study with recommendations for methodology. Pilot families have been followed from recruitment at 15 weeks gestation to six months post-partum. Despite challenges outlined, the feasibility study has demonstrated the acceptability of a cross-generation health study in the community, and enabled optimisation of recruitment, data collection time points and outcome measures. The commitment to undertaking a study of this kind is substantial in terms of costs and time [39], but the value is likewise.

We thank the reviewers for their feedback and believe the manuscript has been improved as a result.
References

