Author's response to reviews

Title: A randomized controlled trial to assess the clinical and cost effectiveness of a nurse-led Antenatal Asthma Management Service in South Australia (AAMS study)

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Version: 4 Date: 7 November 2013

Author's response to reviews: see over
Dear Editor

We thank the reviewers for their informative and thorough feedback and for the opportunity to revise the manuscript in accordance with their suggestions.

Reviewers comment:

1. **Recommendation regarding the use of attention control in standard care arm.**

We appreciate that the reviewer disagrees with our comments regarding the use of an attention control and wish to take this opportunity to highlight that this reflects the disagreement that exists in the general research community. There is significant controversy regarding the use of attention control groups in behavioural intervention research, which is highlighted in a recent editorial published this year. While some researchers advocate for the use of attention controls there is, at this point in time, a significant lack of understanding regarding what constitutes an appropriate attention control group. There is also a lack of understanding regarding the potential benefits (or biases) associated with the use of an attention control. In the context of antenatal care, discussing dietary related issues during a 30 minute consultation with women could introduce bias as any alterations in dietary patterns as a result of this education session could have a significant effect on asthma control and perinatal outcomes, key outcomes of this study.

From a purely pragmatic perspective, the aim of this study is to evaluate whether the implementation of an antenatal asthma management service is associated with improved asthma control during pregnancy. The aim of the study is to determine whether clinically important outcomes can be improved, not to prove the unique value of a particular brand of therapy or to validate its special techniques. As such we believe that the use of a control group that focuses on attention or non-specific effects can defeat the purpose of this pragmatic interventional trial.

We have ensured that we are comparing the intervention to a clinically relevant alternative, such as the current standard of care. For the purposes of adequate data collection, we would like to highlight that women receiving standard care are going to be followed-up more closely at intervals that match those receiving the intervention (6-weekly). While these face-to-face consultations will last for 15 minutes or so, compared to the 45 minute consultations for those in the intervention group, this will incorporate some form of attention control. We recognise
that a potential limitation of our study is that just following up a control group of women with asthma and asking them questions about their asthma control could inadvertently lead to improved asthma management and subsequent control. However, we have made significant efforts to ensure our study has been designed in such a way as to reduce the risk of unintended influences on non-study care, and we have ensured that we will be collecting significant amounts of data in a systematic fashion on ways in which study staff may affect non-study care (e.g., when they urge participants to contact their personal physician about worrisome symptoms). These data, as well as data on the actual receipt of key aspects of non-study care, can be used in secondary analyses to determine whether the outcomes of the trial may have been affected by unintended between-group differences in non-study care.

Therefore, given that equalization of attention between both arms has no guarantees of eliminating unintended differences in non-study care, and conversely, unequal attention does not always cause unintended differences in non-study care, we feel that it is not necessary to change the existing structure of the intervention and control arms of the study.

A short summary of this issue has been included within the description of the standard care arm of the project in the revised manuscript.

“While women receiving standard care will be followed-up at exactly the same time points as those in the intervention group, no formal attentional control will be utilized. Notably, while some researchers advocate for the use of attention controls there is, at this point in time, a significant lack of understanding regarding what constitutes an appropriate attention control group. There is also a lack of understanding regarding the potential benefits (or biases) associated with the use of an attention control, limiting its ability to be utilized in this setting [39].”

We hope that you find this response satisfactory.

Yours sincerely

On behalf of the authors

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