Author's response to reviews

Title: A Randomised Controlled Trial Comparing Standard or Intensive Management of Reduced Fetal Movements after 36 Weeks Gestation - A Feasibility Study

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Version: 2 Date: 4 March 2013

Author's response to reviews: see over
Dear Dr Smith,

Re – Revised Manuscript #1020526359181945 “A Randomised Controlled Trial Comparing Standard or Intensive Management of Reduced Fetal Movements after 36 Weeks Gestation - A Feasibility Study”

The authors are very grateful to the editorial office and reviewers for the comments made in the manuscript. The authors would be grateful if you would consider this revised manuscript for publication in BMC Pregnancy and Childbirth. We have made the following adjustments to the manuscript shown in red.

Reviewer #1

1. Compulsory Revision - The decision of the authors not to publish the outcomes of the pilot study require further consideration. Their reason is valid: the trial was not powered to measure these outcomes, which are thus subject to the play of chance. On the other hand, in the era of reliance on systematic reviews of randomized trials, the principle is that all results for all women randomized to alternative interventions, no matter how small the individual trial, should be available for inclusion in systematic reviews. Otherwise there is the risk that outcomes by chance positive will be reported while those by chance negative will not, leading to publication bias. I would strongly recommend that the authors either include the results (with the necessary caution that they are subject to the play of chance), or indicate that the results will be published elsewhere or made available for systematic review.

Authors’ Response – The authors agree with Reviewer 1s argument. The outcome data were originally presented in table 2, but with little discussion in the text. We have now presented the outcome data in table 4 and added a section in the text on Page 9. We have commented that the study was not powered to detect a difference in perinatal outcome.

2. It may be worth reconsidering the inclusion of SGA in the composite outcome, as it is unlikely to be modified by more or less active management towards the end of the pregnancy.

Authors’ Response – The authors understand the reviewers’ concern that SGA is included in the composite outcome and the various components of the composite are presented as secondary outcomes. The DIGITAT study randomised pregnancies complicated by small for gestational age after 36 weeks gestation to expectant or interventional management reported a difference in birthweight between the two groups which suggests that SGA may alter dependent on management. The link between reduced fetal movements and placental pathology suggests that fetuses managed conservatively might continue to grow at the same rate. Therefore, we believe it is plausible that the proportion of infants with SGA may be...
altered between conventional treatment and our intervention group. However, this is something that we will continue to examine and address in our research studies.

Reviewer #2

1. In the Background section there is reference to a cluster RCT (AFFIRM Study); can the authors provide a reference for this study as it appears to be missing from the reference list.

Authors’ Response – The authors have added the Clinical Trials reference number to the manuscript and a reference to the URL on Page 4.

General Comments

1. A completed CONSORT checklist has been uploaded on a separate file.

2. The figure legend has been deleted from the image file for Figure 2.

This manuscript is not being considered for publication elsewhere. The authors do not have any competing financial or personal interests. All authors fulfil the requirements for authorship status. Thank you for considering this manuscript for publication in BMC Pregnancy and Childbirth.

Yours sincerely,

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