PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	The Complementary Therapies for Labour and Birth Study: A randomised controlled trial of antenatal integrative medicine for pain management in labour
AUTHORS	Levett, Kate; Smith, Caroline; Bensoussan, Alan; Dahlen, Hannah

VERSION 1 - REVIEW

REVIEWER	Kenneth Finlayson University of Central Lancashire UK
REVIEW RETURNED	03-Dec-2015

GENERAL COMMENTS	The authors have highlighted the use of a novel and intriguing intervention that appears to demonstrate a significant impact on key clinical outcomes. There is a need, and currently a political will, to try and reduce rates of medical intervention during labour and birth and the antenatal training programme outlined in this study appears to give some credence to the notion that a targeted, more holistic approach to birth preparedness has the potential to help in this regard. There may be some reservations about the complexity of the intervention and the relative impact of individual components but RCT's of complex interventions do not necessarily seek to identify individual component effects and the authors address these concerns reasonably well. As far as limitations are concerned, the trial is relatively small and despite the authors acknowledgement that generalizability may be an issue I think this could be explored in a bit more detail - previous use of CM is likely to vary widely and may affect acceptance; weekend antenatal training courses for women, partners and health professionals are not the norm in the UK and may affect attendance; and, given the range and scope of intervention components, there are likely to be significant training costs. Are there likely to be copyright issues in any future studies about using the existing programme 'She Births'? Randomization techniques and sample size calculations seem ok. Stat's also seem ok but may need checking carefully as the primary outcome is likely to influence some of the secondary outcomes It would be useful for readers to see a copy of the LAS questionnaire (as a supplement) There are a few typo's that need correcting

REVIEWER	Dr Lisa Yelland The University of Adelaide Australia
REVIEW RETURNED	18-Dec-2015

GENERAL COMMENTS	This article reports the primary and secondary outcomes of a randomised controlled trial comparing an integrative medicine antenatal education program plus standard care with standard care alone. The following revisions are recommended to improve the clarity of the article: 1. The conclusion of the abstract is used to describe the intervention as well as state the conclusions. The description of the intervention should be moved to the methods and intervention section. 2. The participants subsection of the methods indicates that recruitment was undertaken at two hospitals that reflect diverse socio-economic areas and reference is made to supplementary file S1, however there is no socio-economic description of these hospitals in the uploaded supplementary file. 3. The randomisation subsection of the methods provides details on how the randomisation sequence was generated but it is unclear how the randomisations were actually performed (e.g. was a web-based or telephone based randomisation service used?). 4. In the intervention subsection of the methods, what is the intended gestational age range of women when taking the intervention workshop and commencing the usual care antenatal education classes? 5. In the questionnaires subsection of the methods, please provide further details on the LAS, including the range of possible scores and what a higher score indicates. 6. The analysis subsection of the methods indicates that unadjusted analyses were performed. As the randomisation was stratified by site, analyses adjusting for site would be more appropriate and these should be presented instead of or in addition to the unadjusted analyses (see Kahan & Morris, Improper analysis of trials randomised using stratified blocks or minimisation, Statistics in Medicine 2012; 31:328-40). 7. The sample size and power subsection of the methods requires clarification. It is unclear whether the target sample size of 170 included the 20% attrition rate or not. The assumed percentages in the intervention and control groups given in the article do not match the protocol provided as a supplementary file. The final statement that primary outcome data was available for all consenting participants (n=176 randomised) seems to disagree with the flowchart (n=171 analysed). 8. In table 1, the statistical tests performed to compare the treatment groups on baseline characteristics should be removed as any differences are simply the result of chance. 9. The secondary clinical outcomes subsection of the results needs careful revision, since many of the results presented do not match the figures given in table 2. Also, the authors seem to be using Levene's test for equality of variance as some way of addressing the potential bias in the comparison of LAS scores due to the missing data, which is misleading. It would be more helpful to provide information on the baseline characteristics of responders vs non-responders. More information is also needed to support the statement that belly breaths, visualisation and acupressure were identified as being the more utilised techniques - what percentage of

	women in the intervention group used each of the six intervention techniques? 10. The rate of epidural use observed in the control group was much higher than anticipated (69% vs 46%). Can the authors comment on this in the discussion?

REVIEWER	Mary-Ann Davey Judith Lumley Centre, La Trobe University, Australia I have been a co-investigator with CI Smith on a small pilot study, but we have not published together, and have not worked in the same organisation. I have no other conflicts of interest.
REVIEW RETURNED	23-Dec-2015

GENERAL COMMENTS	Thank you for the opportunity to review this very interesting paper. The findings have the potential to generate important further research and changes to antenatal preparation for birth. The flexibility of the program means it can be individualised to a particular women's preferences and situation. I do however have a few questions/suggestions which I hope you find constructive, the most important of which is clarification of the primary outcome. Abstract The primary outcome is said to be 'rate of epidural use'. It needs to be made explicit whether this means only epidurals used for pain relief in labour (analgesia), or whether it also includes those given to enable operative birth (anaesthesia). The secondary outcomes listed do not include all those in the published protocol. Major perineal damage is defined here as 3rd or 4th degree laceration. Elsewhere it is defined as 3rd, 4th degree laceration or episiotomy, and perhaps somewhere else as 2nd, 3rd, 4th degree laceration or episiotomy. Article summary: The abbreviation EDB is used without first providing its full wording. There is a typo in the 5th last line Background The last sentence would fit better in the Methods section. Methods Participants: add the gestation at recruitment. Was a cephalic presentation really a necessary inclusion characteristic at recruitment (i.e. at 24 weeks)?? How were the 315 women screened for eligibility selected? It would help to add boxes to the top of the flow chart to clarify how these 315 were selected from all women giving birth at the hospitals in the period. Similar details should be included about the volunteers from the university posters. The number included from each source would be informative. Randomisation: Please add more detail about the randomisation- were there variable block sizes to reduce selection bias? How did the recruiter access the randomisation – opaque envelopes? telephone? Were there other strategies to prevent recruitment bias e.g. an inability to enter the same woman's details twice for

	randomisation? Intervention: (last paragraph) suggest deleting/moving the second sentence, because antenatal education in Australia generally is not relevant here; rather the details of the antenatal education offered at the 2 study sites is important. Please add their contents and the structure of each so that readers can compare with that offered to the intervention group. A priori outcome measures: explicitly state that epidurals given to facilitate operative birth were excluded (assuming they were). Gestation is not included in the secondary outcomes (as it is in the protocol). It is important to include it given that some techniques were designed to encourage the onset of labour, and were practised from 37 weeks, making it an important safety outcome. Other secondary outcomes need to be defined e.g. PPH, perineal trauma, severe perineal trauma, resuscitation. Sample size and power: This is confusing. The protocol says the trial was powered on a 20% relative reduction in epidural use from 43.5% to 34.8% (based on NSW Mothers and Babies report which I think combines epidural analgesia and epidural anaesthesia?), but the paper says it was based on an absolute reduction of 20% from 46% to 26%. Either way, it would seem that the sample size used was too small (1,290 needed for the first and 250 for the second, allowing for 20% loss to follow up). In the end this is a moot point because of the enormous difference between the groups in use of epidural analgesia, but it should be clarified. Results Paragraph 2 – did women complete the trial entry form prior to randomisation? Para 3- The first sentence might be better expressed as "Participants in the intervention group did not significantly differ from those in the control group in terms of……". The mention of the gestational age and birthweight here properly belong in outcomes, not baseline characteristics. Table 2 – the denominator for perineal trauma, and major perineal trauma specifies NVB as the denominator. It should be 'all vaginal births' (as has clearly been used for the calculations). Secondary clinical outcomes – the word 'statistically' in the first line is redundant. Line 5 – the reduction in second stage is borderline (=0.05 not <0.05) and would be better described as a borderline result throughout. The mention in the next paragraph could be expressed '…for the control group giving a mean difference of 32 minutes…'. Resuscitation by bag and mask is different from resuscitation with oxygen and or suction. Please clarify. Discussion: Paragraph 2 – I suggest that antenatal education has moved in the direction described in some settings only. Some antenatal classes normalise the use of epidural analgesia and caesarean section. Line 6 – are the words 'of effectiveness' missing after 'evidence'?

	Interpretation Line 2 – ‘are’ should be ‘is’ line 3 – I think the word ‘reduced’ is missing before ‘augmentation’.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Kenneth Finlayson
Institution and Country: University of Central Lancashire, UK
Please state any competing interests or state ‘None declared’: None declared

Please leave your comments for the authors below

1. The authors have highlighted the use of a novel and intriguing intervention that appears to demonstrate a significant impact on key clinical outcomes. There is a need, and currently a political will, to try and reduce rates of medical intervention during labour and birth and the antenatal training programme outlined in this study appears to give some credence to the notion that a targeted, more holistic approach to birth preparedness has the potential to help in this regard.
Thank you

2. There may be some reservations about the complexity of the intervention and the relative impact of individual components but RCT's of complex interventions do not necessarily seek to identify individual component effects and the authors address these concerns reasonably well.
The interventions contained within the program are designed to give women, and partners, options for personal preference and for variations that occur in labour, that may be unanticipated, especially for nulliparous women. The actual program, when experienced, all fits together quite well and similar themes run through the workshop – the variety of techniques are all supporting the same end.
Women and partners commonly fed back how much they enjoyed learning the techniques and attending the workshop. Recruitment to this study was relatively quick and easy, reflecting perhaps the desire for this kind of support for women and partners.

3. As far as limitations are concerned, the trial is relatively small and despite the authors acknowledgement that generalizability may be an issue I think this could be explored in a bit more detail - previous use of CM is likely to vary widely and may affect acceptance; weekend antenatal training courses for women, partners and health professionals are not the norm in the UK and may affect attendance; and, given the range and scope of intervention components, there are likely to be significant training costs.
We acknowledge that generalisability is an issue, but also recognise that the demographics of the women who did attend are consistent with those most likely to use both CM and epidural for pain relief. This is the only trial of antenatal education that has demonstrated a reduction in epidural use, among other outcomes.
In the Future Research section we have added:
We are seeking to establish a larger trial in a broader national and international setting whereby issues of implementation and generalisability may be address. As a first stage, these results are promising and we agree further investigation is warranted.

With regard to training costs for broader implementation, we are undertaking an economic analysis, to be published at a later date to establish what these costs are. These techniques are becoming part of birth training in private practice, so it is not unreasonable to embed these in a train the trainer model as is done for routine antenatal education within hospitals. In Australia, routine antenatal education is commonly offered over a weekend workshop and is quite accepted, however there a range of delivery options also available, such as spread over weeknights in a week or a fortnight, or on a particular

weeknight over many weeks. The schedules within hospitals are quite flexible to allow for different delivery. As they cater mostly to first time parents, many of the women are still working, and require flexibility.

4. Are there likely to be copyright issues in any future studies about using the existing programme 'She Births'?
The study program retains a different descriptive name and has been altered to reflect the evidence base. The founder of She Births® is a collaborator on this project, and retains copyright of the She Births® program, which is a privately run course and owned solely by the founder. We have a copyright agreement in place, and the acknowledgements section reflects the agreement in wording. The research program was registered with the name 'Complete Birth', however it has since become apparent that another private group in Australia is using this name. We have changed the name of the study protocol in this paper and other future publications to be descriptive of the intervention rather than using a name. We will now refer to the study program as: the complementary therapies for labour and birth (CTLB) study protocol. This is done to avoid confusion with the original She Births® and the other company using 'Complete Birth'.

5. Randomization techniques and sample size calculations seem ok. Stat's also seem ok but may need checking carefully as the primary outcome is likely to influence some of the secondary outcomes
The Discussion section already states the following:
Univariate results for secondary outcomes should be interpreted with caution however, as these are likely to be related to the primary outcomes of EDB, which has been shown to mediate the effect these secondary outcomes,[36 37].
However, the following text has been added to the Interpretation section to account for the effect that EDB has on other outcomes:
The primary outcome measure of EDB was used for this study, rather than pain scores which are frequently used in other CM studies (2). The objective measure of EDB has been identified as a mediating factor shown to influence labour interventions and mode of birth, which is described in the literature as the cascade of interventions (3-7). The literature highlights the mechanism whereby an initial intervention during labour triggers subsequent interventions to manage the effects of the prior intervention. EDB has been shown to mediate this effect and is associated with outcomes such as augmentation during labour, instrumental vaginal birth, and CS (8). This study demonstrates an impact on rates of EDB, as well as on rates of augmentation, perineal trauma and CS, and therefore may have an effect on the cascade of interventions. Therefore, caution is required when interpreting secondary outcome measures.

6. It would be useful for readers to see a copy of the LAS questionnaire (as a supplement)
This can be provided as a supplementary file

7. There are a few typo's that need correcting
Thank you, this has been reviewed

Reviewer: 2
Reviewer Name: Dr Lisa Yelland
Institution and Country: The University of Adelaide, Australia
Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

This article reports the primary and secondary outcomes of a randomised controlled trial comparing an integrative medicine antenatal education program plus standard care with standard care alone. The following revisions are recommended to improve the clarity of the article:

1. The conclusion of the abstract is used to describe the intervention as well as state the conclusions. The description of the intervention should be moved to the methods and intervention section.
Thank you, this has been changed in the manuscript to reflect this advice. In the Abstract, the Methods and Intervention section, and the Conclusion section now reads:
Methods and Intervention: The Complementary Therapies for Labour and Birth protocol……
incorporated six evidence-based complementary medicine (CM) techniques; acupressure, relaxation and visualisation, breathing, massage, yoga techniques, and facilitated partner support. Randomisation occurred at 24-36 weeks' gestation, and participants attended a two-day weekend workshop style antenatal education program, plus standard care, compared with standard care alone.
Conclusion: The complementary therapies for labour and birth study protocol significantly reduced epidural use and caesarean section. This study provides evidence for integrative medicine as an effective adjunct to antenatal education and contributes to the body of best practice evidence.

2. The participants subsection of the methods indicates that recruitment was undertaken at two hospitals that reflect diverse socio-economic areas and reference is made to supplementary file S1, however there is no socio-economic description of these hospitals in the uploaded supplementary file. Reference to a supplementary file here is in error. The text is meant to state only: The two hospitals are from diverse areas of Sydney.
3. The randomisation subsection of the methods provides details on how the randomisation sequence was generated but it is unclear how the randomisations were actually performed (e.g. was a web-based or telephone based randomisation service used?).
The word 'web-based' has been inserted in the first line of the first paragraph under the 'Randomisation' section for clarity:
We used a web-based computer generated randomisation sequence prepared centrally via the 'Sealed Envelope' website (https://www.sealedenvelope.com), and concealed centrally.
However, we think that stating that Sealed Envelope is a website is clear.

4. In the intervention subsection of the methods, what is the intended gestational age range of women when taking the intervention workshop and commencing the usual care antenatal education classes?
We have added 'prior to 36 weeks' gestation' to the following sentence under the Intervention section.
A total of 20 workshops were conducted during this time. Participants attended prior to 36 weeks' gestation with a birth partner, and there was a maximum of 12 couples and a minimum of two couples at each workshop, with an average of eight couples per workshop.

5. In the questionnaires subsection of the methods, please provide further details on the LAS, including the range of possible scores and what a higher score indicates.
The LAS has Included in a Supplementary File. We have also added to the Methods section the following:
The LAS contains 29 questions with a 7 point Likert-scale ranging from '1= almost always', to '7= rarely'. Therefore scores could theoretically range from 29, indicating the most agency possible, to a high score of 203 indicating the lowest agency possible.

6. The analysis subsection of the methods indicates that unadjusted analyses were performed. As the randomisation was stratified by site, analyses adjusting for site would be more appropriate and these should be presented instead of or in addition to the unadjusted analyses (see Kahan & Morris, Improper analysis of trials randomised using stratified blocks or minimisation, Statistics in Medicine 2012; 31:328-40).
Thank you for this information. A sub-group analysis demonstrated a similar benefit at each of the three socioeconomically diverse sites (RR=0.27 [0.12-0.60], RR=0.31 [0.11-0.90], RR=0.39 [0.23-0.65]).

The section 'Primary outcome' has been amended as follows.

A statistically and clinically significant reduction in epidural rate was found for the intervention group compared with the control group. The overall unadjusted rate of EDB in the control group was 68.7%, and 23.9% in the study group (risk ratio (RR) = 0.35 [0.23-0.52] p=<0.0001), (Table 2). In addition to stratification of randomisation by site, a post-hoc analysis was performed for each site. The risk ratios for each site were similar to the primary analysis (RR1=0.27 [0.12-0.60], RR2=0.31 [0.11-0.90], RR3=0.39 [0.23-0.65]).

7. The sample size and power subsection of the methods requires clarification. It is unclear whether the target sample size of 170 included the 20% attrition rate or not. The assumed percentages in the intervention and control groups given in the article do not match the protocol provided as a supplementary file. The final statement that primary outcome data was available for all consenting participants (n=176 randomised) seems to disagree with the flowchart (n=171 analysed).
The sample size calculation was originally performed using an estimated 20% relative reduction in epidural rates. The statistician then advised us that an absolute reduction was feasible for the study. The sample size calculation based on a 20% absolute reduction in EDB rates yielded a sample size of 170. We continued with randomisation until we had at least 170 women with outcomes available for analysis. A 20% attrition rate would have required randomising 204 women. However, as the trial commenced, recruitment was popular and the attrition rate was less than anticipated and only 5 women were lost to follow up. We were able to monitor how many women dropped out as the trial was ongoing. We randomised 176 women, and accounted for these 5 women lost to follow up by a best-case, worst-case analysis. There were 171 women included in the final analysis.
The section under Sample size and power now reads
Recruitment continued until at least 170 women had been enrolled, and those randomised to the treatment group had either completed the course or were known to have missed their course, with 176 randomised and 171 completing the study. A low drop-out rate (<3%) was observed…

8. In table 1, the statistical tests performed to compare the treatment groups on baseline characteristics should be removed as any differences are simply the result of chance.
This information has been deleted.

9. The secondary clinical outcomes subsection of the results needs careful revision, since many of the results presented do not match the figures given in table 2.
Thank you - Results presented have been reviewed to be consistent with figure.
Also, the authors seem to be using Levene's test for equality of variance as some way of addressing the potential bias in the comparison of LAS scores due to the missing data, which is misleading. It would be more helpful to provide information on the baseline characteristics of responders vs non-responders.
Thank you – a post-hoc analysis has been performed to determine if there were any differences in baseline characteristics present for the study group and the control group when stratified as responders and non-responders. There were no differences in the baseline characteristics between these groups, indicating that the groups remained comparable.
The following has been added to the 4th last paragraph of the Secondary Outcomes:
Additionally, we did a post-hoc analysis to determine if any differences were present between the study group and the control group for baseline characteristics, controlling for responders vs non-responders. No differences were found between groups.

More information is also needed to support the statement that belly breaths, visualisation and acupressure were identified as being the more utilised techniques - what percentage of women in the intervention group used each of the six intervention techniques?
The following has been added to the last paragraph of the Results section:
To examine if there was any preference for therapies used during labour, we asked women in the

study group (n=88) what specific CM therapies they used during labour. On average, women used 3.94 (SD=1.4) techniques over the duration of their labour, and in order of frequency used, Belly Breaths were used most frequently, by 60.2% of women; visualisation was used by 55.7%; acupressure by 46.6%; yoga and massage each by 45.5% of women; and Gentle Birthing Breaths were used by 35.2% of women during labour.
The following was already in the Results section preceding the sentence above:
Women in the control group did not report antenatal practice of techniques, but some (<5%) did report using techniques such as breathing or visualisation during the labour.

10. The rate of epidural use observed in the control group was much higher than anticipated (69% vs 46%). Can the authors comment on this in the discussion?
Thank you for the comment, the following text has been added to the Discussion section:
We note that women in the control group experienced a higher than average rate of EDB use, augmentation and instrumental vaginal birth, which is consistent with data showing higher rates of intervention for primiparous women compared with multiparous women (3). The data for EDB use in this study are consistent with rates for women who are identified as being anxious (4, 5). Further research is needed to identify if women who are anxious are more likely to participate in antenatal education programs, and whether these women may benefit more from this type of intervention.

Reviewer: 3
Reviewer Name: Mary-Ann Davey
Institution and Country: Judith Lumley Centre, La Trobe University, Australia
Please state any competing interests or state 'None declared': I have been a co-investigator with CI Smith on a small pilot study, but we have not published together, and have not worked in the same organisation. I have no other conflicts of interest.

Please leave your comments for the authors below

Thank you for the opportunity to review this very interesting paper.
The findings have the potential to generate important further research and changes to antenatal preparation for birth. The flexibility of the program means it can be individualised to a particular women's preferences and situation.
I do however have a few questions/suggestions which I hope you find constructive, the most important of which is clarification of the primary outcome.

1. Abstract
The primary outcome is said to be 'rate of epidural use'. It needs to be made explicit whether this means only epidurals used for pain relief in labour (analgesia), or whether it also includes those given to enable operative birth (anaesthesia).
The abstract has been amended to state:
Main outcome measures: Rate of analgesic epidural use.

2. The secondary outcomes listed do not include all those in the published protocol.
This has been discussed in reviewer 2's comment 1

3. Major perineal damage is defined here as 3rd or 4th degree laceration. Elsewhere it is defined as 3rd, 4th degree laceration or episiotomy, and perhaps somewhere else as 2nd, 3rd, 4th degree laceration or episiotomy.
We have identified two inconsistencies where episiotomy was not included in the definition of major perineal trauma, and have added the word 'episiotomy' to the definition where it appears in the text.

4. Article summary: The abbreviation EDB is used without first providing its full wording.
There is a typo in the 5th last line
Thank you, previously changed to previous.

5. Background
The last sentence would fit better in the Methods section.
This sentence is a statement of the study aims to sum up the background information presented, and the rationale for the trial. If the editor agreed it should be moved, this can be done.

6. Methods
Participants: add the gestation at recruitment. Was a cephalic presentation really a necessary inclusion characteristic at recruitment (i.e. at 24 weeks)?? How were the 315 women screened for eligibility selected? It would help to add boxes to the top of the flow chart to clarify how these 315 were selected from all women giving birth at the hospitals in the period. Similar details should be included about the volunteers from the university posters. The number included from each source would be informative.
Thank you for your comment, however, it is stated that all eligible women, who were nulliparous, between the given gestations and low risk, were approached in the antenatal clinic according to the eligibility criteria. There were no further criteria upon which women were screened. Details are given about refusals, including 109 who declined to participate for undisclosed reasons. To specify cephalic presentation, we were being very cautious as breech remains a risk factor until birth. This criterion aimed to exclude women whose babies were already in a breech as this was an indication for caesarean section at these two hospitals. Most women were approached when they were closer to 30 weeks, and women remained eligible until 34 weeks if the baby moved into a cephalic position. However, we can include the following statement in the first paragraph of the Results section: In the final analysis, there were 101 women included from site 1, 30 women from site 2, and 40 women from site 3.
We have also included the following statement in the Participant section in the Methods section.
All eligible women were approached in the antenatal clinic at site 1, as this was a smaller unit, individual contact was possible, and all clinics were attended regularly by the researcher. At site 2, the hospital was much larger, and more diverse with regard to structure of the clinics. Different clinics were attended, and eligible women at those clinics were approached. It was not possible to attend all clinics at this larger unit, and a range of clinics were selected on different weeks to achieve a representative sample of women. For site 3, where flyers and newspaper advertisements were used for recruitment, the response rate was quite low. All eligible women who contacted us through these means were randomised to the study. We do not have data on the women who were not eligible to participate. The randomisation target was achieved quite quickly, and participation was popular.

7. Randomisation: Please add more detail about the randomisation- were there variable block sizes to reduce selection bias? How did the recruiter access the randomisation – opaque envelopes? telephone? Were there other strategies to prevent recruitment bias e.g. an inability to enter the same woman's details twice for randomisation?
This has been addressed. It is a web-based randomisation service. As the researcher KL was the only person who recruited and randomised women, and conducted the weekend programs, she was well aware of those who had been already randomised.
The following sentence has been added to the list of exclusion criteria:
Had insufficient English, or had been previously randomised to the trial.

8. Intervention: (last paragraph) suggest deleting/moving the second sentence, because antenatal education in Australia generally is not relevant here; rather the details of the antenatal education

offered at the 2 study sites is important. Please add their contents and the structure of each so that readers can compare with that offered to the intervention group.
Thank you for your comment. Women were recruited at 3 sites, and those from the UWS site represented 12 different hospitals in NSW. There were a range of antenatal education classes that were attended and were quite diverse. We have attempted to summarise the main themes covered as they were similar in many ways. These have been outlined in the text. This pragmatic study is not attempting to evaluate usual care, only stating that women proceeded as usual with routine antenatal care. Randomisation should account for the differences in usual care.

9. A priori outcome measures: explicitly state that epidurals given to facilitate operative birth were excluded (assuming they were).
Anaesthesia provided for operative births were generally referred to as spinal blocks, and not epidural blocks. These were identified by timing of administration of the EDB or spinal. We aimed to identify all cases where EDB was used as analgesia not anaesthesia. There may have been some cross over and, as the literature states, operative delivery may be associated with the initial epidural, and as such is part of the cascade of interventions.

10. Gestation is not included in the secondary outcomes (as it is in the protocol). It is important to include
It is stated in the last paragraph under Results and following the flow chart:
Babies were not different in terms of average gestational age or weight at birth.

11. it given that some techniques were designed to encourage the onset of labour, and were practised from 37 weeks, making it an important safety outcome.
There was no difference in gestational age and onset of labour.
We have added to the 4th paragraph of the Discussion:
Techniques were rehearsed in the antenatal period with some acupressure for induction techniques practiced lightly from 37 weeks as per the published literature,55. This is reported to work with the hormones that are naturally present in the woman's body, but do not artificially induce contractions. This is an important safety outcome, and there were no differences in gestational age at birth.

12. Other secondary outcomes need to be defined e.g. PPH, perineal trauma, severe perineal trauma, resuscitation.
This has been clarified in the secondary outcomes section

13. Sample size and power: This is confusing. The protocol says the trial was powered on a 20% relative reduction in epidural use from 43.5% to 34.8% (based on NSW Mothers and Babies report which I think combines epidural analgesia and epidural anaesthesia?), but the paper says it was based on an absolute reduction of 20% from 46% to 26%. Either way, it would seem that the sample size used was too small (1,290 needed for the first and 250 for the second, allowing for 20% loss to follow up). In the end this is a moot point because of the enormous difference between the groups in use of epidural analgesia, but it should be clarified.
This has been clarified in previous comments.

14. Results
Paragraph 2 – did women complete the trial entry form prior to randomisation?
No, women were randomised before any questionnaires were completed (as stated in line 3 of the Results section).

15. Para 3- The first sentence might be better expressed as "Participants in the intervention group did not significantly differ from those in the control group in terms of……". The mention of the gestational age and birthweight here properly belong in outcomes, not baseline characteristics.

Thank you for the comment. This sentence has been amended.
The mention of gestational age etc has been previously amended to sit here. Please advise as to preferred location.

16. Table 2 – the denominator for perineal trauma, and major perineal trauma specifies NVB as the denominator. It should be 'all vaginal births' (as has clearly been used for the calculations).
Thank you, this has been amended.

17. Secondary clinical outcomes – the word 'statistically' in the first line is redundant.
Line 5 – the reduction in second stage is borderline (=0.05 not <0.05) and would be better described as a borderline result throughout.
The statement says 'reduced', which is correct.
18. The mention in the next paragraph could be expressed '…for the control group giving a mean difference of 32 minutes…'.
This has been amended

19. Resuscitation by bag and mask is different from resuscitation with oxygen and or suction. Please clarify.
Thank you – we have clarified in the secondary outcomes sections and in table 2 and have amended as follows:
Babies of women in the study group were also less likely to require resuscitation by suction (plus or minus oxygen) or with bag and mask (RR=0.47 [95% C.I.:0.25-0.87], p=0.015). There were no differences in the rare outcomes of intubation or cardiac massage required at birth?

20. Discussion:
Paragraph 2 – I suggest that antenatal education has moved in the direction described in some settings only. Some antenatal classes normalise the use of epidural analgesia and caesarean section. This is a general statement reflecting the current literature currently in Australia that emphasises parent education (6-8).
21. Line 6 – are the words 'of effectiveness' missing after 'evidence'?
No

22. Interpretation
Line 2 – 'are' should be 'is'
Amended

line 3 – I think the word 'reduced' is missing before 'augmentation'.
Amended

VERSION 2 – REVIEW

REVIEWER	Kenneth Finlayson University of Central Lancashire, Preston, UK
REVIEW RETURNED	05-Apr-2016

GENERAL COMMENTS	From my perspective, the authors have addressed all of the issues raised during the initial review process. There are a couple of minor grammatical errors which need to be addressed prior to publication:- 1. Page 3 (line 57) - the sentence should read '....an a priori hypothesis....' 2. Page 4 (line 27) - the sentence should read, '...are also amongst.....'

	Could the authors also confirm that their adaptation and use of the 'SheBirths' programme does not raise any copyright or IP issues.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Kenneth Finlayson
Institution and Country: University of Central Lancashire, Preston, UK
Competing Interests: None Declared

From my perspective, the authors have addressed all of the issues raised during the initial review process.
There are a couple of minor grammatical errors which need to be addressed prior to publication:-
1. Page 3 (line 57) - the sentence should read '....an a priori hypothesis....'
2. Page 4 (line 27) - the sentence should read, '...are also amongst.....'
Thank you. These have been amended, and highlighted with track changes in the paper

Could the authors also confirm that their adaptation and use of the 'SheBirths' programme does not raise any copyright or IP issues.
The use of the She Births® program has been done with the consent of the person who developed it, and we have no IP issues.

Correction: *Complementary therapies for labour and birth study: a randomised controlled trial of antenatal integrative medicine for pain management in labour*

Levett KM, Smith CA, Bensoussan A, *et al*. Complementary therapies for labour and birth study: a randomised controlled trial of antenatal integrative medicine for pain management and labour. *BMJ Open* 2016;6:e010691 doi:10.1136/bmjopen-2015-010691.

There are several amendments to this article:

Reference 23 should be Betts D. Acupressure techniques for use during childbirth and pregnancy. http://acupuncture.rhizome.net.nz (accessed 2015 2005).

The sentence: Acupressure,[22 24] which uses six main points for use during labour selected from a previously published protocol.[23] These focus on hormone release for labour progression, augmentation of contractions, pain relief, nausea and positioning of baby.

Should read: Acupressure, [22 24] which uses six main points for use during labour selected from a previously published protocol.[23] The participants were given DVDs of the acupressure protocol[23] to take home for practice. These focus on hormone release for labour progression, augmentation of contractions, pain relief, nausea and positioning of baby.

The sentence: The LAS contains 29 questions with a seven-point Likert scale ranging from '1=almost always', to'7=rarely'. Therefore, scores could theoretically range from 29, indicating the highest control possible, to a high score of 203 indicating the lowest agency possible.

Should read: The LAS contains 29 questions with a seven-point Likert scale ranging from '1=almost always', to'7=rarely'. Therefore, scores could theoretically range from 29, indicating the lowest control possible, to a high score of 203 indicating the highest agency possible.

The acknowledgements have been corrected to include: Dr Debra Betts provided the acupressure protocol for labour and birth and can be accessed at this address: https://acupuncture.rhizome.net.nz/). Dr Debra Betts (debra.betts@rhizome.net.nz) and Tom Kennedy (tzkennedy@hotmail.com) provided the DVD for the study participants. None were directly involved in this study.

Reference 1 in the supplementary data has been corrected to:

Reference 1: Betts D. Acupressure techniques for use during childbirth and pregnancy. http://acupuncture.rhizome.net.nz (accessed 2015 2005).

BMJ Open 2016;**6**:e010691corr1. doi:10.1136/bmjopen-2015-010691corr1