NOTICE: This document contains correspondence generated during peer review and subsequent revisions but before transmittal to production for composition and copyediting:

- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)*

*The corresponding author has opted to make this information publicly available.

Personal or nonessential information may be redacted at the editor’s discretion.

Questions about these materials may be directed to the Obstetrics & Gynecology editorial office: obgyn@greenjournal.org.
RE: Manuscript Number ONG-19-1550

Fetal movement counting and perinatal mortality: a systematic review and meta-analysis

Dear Dr. Berghella:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. Although it is judged not acceptable for publication in Obstetrics & Gynecology in its present form, we would be willing to give further consideration to a revised version.

If you wish to consider revising your manuscript, you will first need to study carefully the enclosed reports submitted by the referees and editors. Each point raised requires a response, by either revising your manuscript or making a clear and convincing argument as to why no revision is needed. To facilitate our review, we prefer that the cover letter include the comments made by the reviewers and the editor followed by your response. The revised manuscript should indicate the position of all changes made. We suggest that you use the "track changes" feature in your word processing software to do so (rather than strikethrough or underline formatting).

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Oct 11, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: This is a carefully done systematic review of RCTs regarding the whether the use of antenatal decreased fetal movement protocols during pregnancy affects perinatal mortality. Since this is a relatively ubiquitous practice in obstetric care without definitive data that this practice changes outcome, the question is clinically relevant as well as possibly relevant regarding fetal pathophysiology.

I have the following concerns:
1. 82% of the patient population came from a single study which has been published in the Lancet 2018, and the results from this 2018 published study did not vary significantly from the results reported in the systematic review.
2. There was significant variation among studies including inclusion and exclusion criteria, gestational age at randomization, and particularly in the instructions given to the intervention group which makes it difficult to interpret or generalize the review's findings given the diversity of the patient population and instruction method.

Reviewer #2: A systematic review To assess the efficacy of fetal movement counting (FMC) for prevention of perinatal mortality

Findings: no statistical differences in stillbirths, neonatal deaths, birthweight less than 10th percentile, reported DFM, APGAR at 5 minutes < 7, NICU

significant increases in preterm delivery (7.6% vs 7.1%; RR 1.07, 95% CI 1.05 to 1.10), induction of labor (36.6% vs 31.6%; RR 1.15, 95% CI 1.09 to 1.22), and cesarean delivery (28.2% vs 25.3%; RR 1.11, 95% CI 1.10 to 1.12).

Discussion Please address

Is the decrease in mortality of 8% in the FMC group clinically significant? many would argue it is.

DFM might be helpful in more than simply stillbirth, Perhaps it signifies an untoward event occurring in utero which is why there are more interventions. Can you discuss?

The tone is that these are unnecessary interventions. Maybe they are preventing morbidity or are they causing more morbidity because of unnecessary interventions?
Reviewer #3:

- Elaboration on the various definitions of decreased fetal movement would be helpful to the reader introduced to this topic.

- Were the text words searched in the literature search MeSH terms?

- Was the Grey literature searched?

- How was consensus reached when assessments differed between the two independent authors? Was an instrument/tool used? Please elaborate.

- Twin pregnancies are higher risk than singleton and fetal movement counting can be more challenging in twin pregnancies. I question the validity of combining trials that had singletons and trials that had twin pregnancies in this systematic review.

- Although the combined sample size is high, as only a few of the studies included actually looked at stillbirth (primary outcome) as an outcome, your study might still be underpowered. Was a sample size calculation completed?

Reviewer #4: This manuscript reports a systematic review and meta-analysis of the literature regarding the use of fetal movement counting to prevent still birth. This is an important topic given that this intervention is widely used. There is significant heterogeneity in the publish literature regarding FMC. Also, as the authors note the impact on stillbirth rates is difficult to assess given the rarity of the outcome, but readers will find the results of the study interesting given that such a seemingly benign intervention may lead to iatrogenic co-morbidity. Some suggested revisions are listed below.

1. Introduction: The author’s note the association between DFM and poor outcomes, however still birth would be the result of those pregnancy complications listed. Can the author’s comment on the rates of DFM in uncomplicated pregnancies versus those with complications known to be associated with DFM?

2. Study: What are the exclusion criteria? What was the most common reason for exclusion?

3. Results: In the introduction it is mentioned that a large sample size is needed evaluate the outcome of stillbirth. Did the sample size from the 5 RCTs evaluated reach the predicted sample size?

4. Discussion: There heterogeneity in the etiology of DFM should be discussed in the limitations. Should a prospective study stratify the groups by risk? It seems the counseling would be different in a low risk versus a high risk group.

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

lines 48-49: Need to clarify whether the RR = .92 had p within or outside the 95% CI. Later comments (lines 124-126) imply that it was outside the 95% CI. If so, then it was simply NS, just as the all the other neonatal outcomes cited on lines 49-51. That is, there was no trend, it was simply NS from these data.

General and Table 3: Although the perinatal outcomes of death, stillbirth, neonatal death are each NS, they also are rare events and despite the large samples, one cannot generalize the NS conclusions. For example, using a control group risk of 0.54% and 200,000 in each cohort, the detectable alternative RR would be < 0.88 or > 1.12, assuming 80% power. For the less frequent outcomes of stillbirth or neonatal death, the detectable alternative RRs are even wider. That is, even with the expanded data base, these conclusions are not just NS, but under powered.

Figs 3, 5: These simply recapitulate the findings of the study by Norman 2018, since almost all data were from that study and did not change the conclusions.
Figs 3, 4, 5: Two of these meta analyses include only 2 studies, so the estimation of I² to assess heterogeneity has insufficient power and the assessment of heterogeneity cannot be generalized. For the third meta analysis, there were only 3 studies, so the power was very limited to make any firm conclusion re: heterogeneity.

EDITOR COMMENTS:

1. Dear Vincenzo:

Thank you for submitting your meta-analysis of research on fetal movement counting. As you know, it is nearly ubiquitous in the US for women to be instructed to count their fetal movements—there is even “an app for that”! However, as you will see from the reviews, we disagree with the findings of your report. The reason is that 82% of your included participants were from a single paper, negating the ability to do a meaningful meta analysis since the other data from much smaller studies will be dwarfed by this one. You could present this as a systematic review, without a meta analysis.

As well, your primary outcome was negative and needs to be presented as such.

My conclusion from reading your paper is that the large recent paper is quite robust and begs to be confirmed—that there is not good data available on the important question of benefits of fetal movement counting. There’s just not much “there, there” other than the one big trial. (Norman JE, Heazell AEP, Rodriguez A et al. Awareness of fetal movements and care package to reduce fetal mortality (AFFIRM): a stepped 177 wedge, cluster-randomised trial. Lancet. 2018;392(10158):1629-1638)

2. In addition to the comments from the reviewers above, you are being sent a notated PDF that contains the Editor’s specific comments. Please review and consider the comments in this file prior to submitting your revised manuscript. These comments should be included in your point-by-point response cover letter.

***The notated PDF is uploaded to this submission’s record in Editorial Manager. If you cannot locate the file, contact Randi Zung and she will send it by email - rzung@greenjournal.org.***

- We no longer require that authors adhere to the Green Journal format with the first submission of their papers. However, any revisions must do so. I strongly encourage you to read the instructions for authors (the general bits as well as those specific to the feature-type you are submitting). The instructions provide guidance regarding formatting, word and reference limits, authorship issues, and other things. Adherence to these requirements with your revision will avoid delays during the revision process, as well as avoid re-revisions on your part in order to comply with the formatting.

- We do not allow authors to describe something as non significant as in any way different between two groups—ie, no “trends”.

- Counting fetal movement would not prevent mortality—its doing so, reporting the results and having some action done. One could say something like “to assess the association of fetal movement counting with perinatal mortality” as an objective.

- when was search begun? At inception of data base?

- In the other 2 were no instructions given? Please describe.

- Sentence beginning on line 49 should read: “There was no difference in perinatal outcome between groups....”

- Apgar is a woman's name, not an acronym and should not be capitalized like this.

- Please note that effect sizes (RR, OR) within the zone of potential bias should be noted as weak. Those effect sizes in the zone of potential interest should be emphasized. (Ref: False alarms and pseudo-epidemics. The limitations of observational epidemiology. Grimes DA, Schulz KF. Ob Gyn 2012;120:920-7)

- rewrite conclusion to show NO difference in primary outcomes and marginally increased rates of secondary outcomes.

- emergency department or labor and delivery.

- What does "Which" refer to here--adverse perinatal outcome or increased uterine artery Doppler results? You have already articulated the association w/ adverse perinatal outcomes (line 73-74) and since ut. Artery Dopplers not done in the US very much, not clear at all what sentence staring on line 74 adds.
- recommended by whom?

- not sure what you mean: comparing protocols and no such protocols? Do you mean RCT’s comparing women randomized to receive instructions for fetal movement counting versus NOT receiving such instructions?

- monitor fetal movement in some fashion ....

- delete highlighted. I thought stillbirth and neonatal death were primary outcomes...why are they listed here as secondary outcomes?

- what gestational age used as lower bound for stillbirth?

- is this included CTG AND US or CTG OR Ultrasound?

- not prior comments re: negative results (ie, no difference between groups, eliminating reference to trends.).

- women given instructions on fetal movement counting had no significant difference in perinatal mortality compared to those who did not receive instructions.

- marginally increased rates of preterm birth....., all within the zone of potential bias.

- not necessary; delete highlighted.

- Your discussion should largely focus on the poor quality, as shown by your study, of the data that underpins this nearly ubiquitous component of prenatal care.

- how many of currently included 5 studies were in this previous one?

- Just like your study.....they found no differences.

- its not really unclear. there is no data to support the use of FMC to prevent perinatal death. But, the data is not perfect. Please do some assessment of the paper that contributed 82% of patients. Was it a good paper? What was it’s risk of bias, etc?

- delete the highlighted line

- please edit consistent w prior comments.

3. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
   A. OPT-IN: Yes, please publish my point-by-point response letter.
   B. OPT-OUT: No, please do not publish my point-by-point response letter.

4. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.

5. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration statement from the manuscript's lead author. The statement is as follows: "The lead author* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained."

   *The manuscript’s guarantor.

If you are the lead author, please include this statement in your cover letter. If the lead author is a different person, please ask him/her to submit the signed transparency declaration to you. This document may be uploaded with your submission in Editorial Manager.

6. Please orient your submission to Portrait instead of Landscape.

7. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was
convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric and gynecology data definitions at https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

8. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Review articles should not exceed 25 typed, double-spaced pages (6,250 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

9. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

* All financial support of the study must be acknowledged.
* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

10. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Reviews, 300 words; . Please provide a word count.

11. Only standard abbreviations and acronyms are allowed. A selected list is available online at http://edmgr.ovid.com/ong/accounts/abbreviations.pdf. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

12. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

13. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%).

14. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If on the other hand, it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

15. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

16. Figures 1-5 may be resubmitted as-is with the revision.

17. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at http://links.lww.com/LWW-ES/A48. The cost for publishing an article as open access can be found at http://edmgr.ovid.com/acad/accounts/ifauth.htm.
Please note that if your article is accepted, you will receive an email from the editorial office asking you to choose a publication route (traditional or open access). Please keep an eye out for that future email and be sure to respond to it promptly.

18. If you choose to revise your manuscript, please submit your revision through Editorial Manager at http://ong.editorialmanager.com. Your manuscript should be uploaded in a word processing format such as Microsoft Word. Your revision’s cover letter should include the following:
   * A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf), and
   * A point-by-point response to each of the received comments in this letter.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors and that each author has given approval to the final form of the revision.

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Oct 11, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

2018 IMPACT FACTOR: 4.965
2018 IMPACT FACTOR RANKING: 7th out of 83 ob/gyn journals

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: https://www.editorialmanager.com/ong/login.asp?a=r). Please contact the publication office if you have any questions.
The Editor

To Whom It May Concern:

Please find attached an amended version of our manuscript according to the reviewers’ comments. We are very grateful to the reviewers for the helpful suggestions. The lead author (Dr Bellussi) and Corresponding author (Dr Berghella) both affirm that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained. A Point-by-point response has been provided below.

REVIEWER COMMENTS:

Reviewer #1: This is a carefully done systematic review of RCTs regarding the whether the use of antenatal decreased fetal movement protocols during pregnancy affects perinatal mortality. Since this is a relatively ubiquitous practice in obstetric care without definitive data that this practice changes outcome, the question is clinically relevant as well as possibly relevant regarding fetal pathophysiology. We thank the reviewer for the kind comments.

I have the following concerns:
1. 82% of the patient population came from a single study which has been published in the Lancet 2018, and the results from this 2018 published study did not vary significantly from the results reported in the systematic review. Thank you for your comment. We have described this as the biggest limitation of our study in the Discussion.

2. There was significant variation among studies including inclusion and exclusion criteria, gestational age at randomization, and particularly in the instructions given to the intervention group which makes it difficult to interpret or generalize the review’s findings given the diversity of the patient population and instruction method. Inclusion criteria were similar, mostly singleton gestations, and exclusion criteria were also similar, mostly fetal anomalies (Table 1). Gestational age did vary between 17 and 32 weeks (Table 1), and instructions all involved movement counting, but did indeed differ somewhat (Table 2). We agree that these are relevant limits of our meta-analysis and, unfortunately, they are present also in the previous meta-analysis performed on this topic. We have added this
Reviewer #2: A systematic review To assess the efficacy of fetal movement counting (FMC) for prevention of perinatal mortality
Findings: no statistical differences in stillbirths, neonatal deaths, birthweight less than 10th percentile, reported DFM, APGAR at 5 minutes < 7, NICU. Significant increases in preterm delivery (7.6% vs 7.1%; RR 1.07, 95% CI 1.05 to 1.10), induction of labor (36.6% vs 31.6%; RR 1.15, 95% CI 1.09 to 1.22), and cesarean delivery (28.2% vs 25.3%; RR 1.11, 95% CI 1.10 to 1.12).

Discussion Please address:
1. Is the decrease in mortality of 8% in the FMC group clinically significant? Many would argue it is.
We have modified the sentences in the Discussion as such: “We found no effect on perinatal mortality by monitoring fetal movements: while the 8% decrease in its incidence between intervention group and controls was not statically significant, some could argue that it could be clinically significant.”

2. DFM might be helpful in more than simply stillbirth, Perhaps it signifies an untoward event occurring in utero which is why there are more interventions. Can you discuss?
We have added this text to the Discussion: “The real utility of these interventions is unclear. On one hand, fetal movement counting could increase concern about fetal wellbeing, leading to higher rate of unnecessary obstetric intervention. On the other hand, reduced fetal movement has been associated not only with stillbirth and perinatal death, but also with a wide range of fetal complications as growth restriction, placental insufficiency, fetomaternal hemorrhage, and congenital anomalies: maybe the increased rate of induction of labor and cesarean section contributes in preventing neonatal morbidity.”

3. The tone is that these are unnecessary interventions. Maybe they are preventing morbidity or are they causing more morbidity because of unnecessary interventions?
See answer to above question.

Reviewer #3:
1. Elaboration on the various definitions of decreased fetal movement would be helpful to the reader introduced to this topic.
Thank you for your comment. We have added information about decreased fetal movement in the Introduction: “Many definitions of decreased fetal movement have been proposed, both quantitative and qualitative, and none of them has been universally accepted\(^1\)\(^-\)\(^3\). Among these, one of the most frequently adopted is “less than 10 movements within 2 hours”; other authors consider reduced fetal movement in case of total absence of fetal movement for a whole day.”

2. **Were the text words searched in the literature search MeSH terms?**
   Thank you for your comment. We have added the MeSH terms searched in the text: “Search terms used were the following text words: “fetal movements”, fetal movements counting”, “fetal kick counting”, “stillbirth”, “fetal demise”, “fetal mortality”, “perinatal death”, of which fetal movement, stillbirth, fetal mortality, and perinatal mortality, were MeSH terms.”

3. **Was the Grey literature searched?**
   Thank you for your comment. Yes, it was. For example, we searched clinical trials.gov.

4. **How was consensus reached when assessments differed between the two independent authors? Was an instrument/tool used? Please elaborate.**
   Thank you for your comment. We have explained better this aspect in the text: “Disagreement between reviewers were discussed and resolved with a third reviewer (VB) through discussion.”

5. **Twin pregnancies are higher risk than singleton and fetal movement counting can be more challenging in twin pregnancies. I question the validity of combining trials that had singletons and trials that had twin pregnancies in this systematic review.**
   Thank you for your comment. We agree with the reviewer that this is a significant limit of the included studies. The majority of the studies included only singletons (Table 1). We added this sentence to cover this issue in the Discussion: “While most studies included only singleton gestations, two included both singletons and twins, and percentages of each populations in these studies was not available, even upon request to the authors.”

6. **Although the combined sample size is high, as only a few of the studies included actually looked at stillbirth (primary outcome) as an outcome, your study might still be underpowered. Was a sample size calculation completed?**
   As this was a meta-analysis of existing studies in the literature, no sample size calculation was done before the meta-analysis was started. A post-hoc sample size calculation reveals that 352,038 fetuses would be needed to show a significant difference between incidences of perinatal deaths of 0.54% to 0.59%, using power of 80% an p of 5%. We have included n the discussion the possible power limitation.
Reviewer #4: This manuscript reports a systematic review and meta-analysis of the literature regarding the use of fetal movement counting to prevent still birth. This is an important topic given that this intervention is widely used. There is significant heterogeneity in the publish literature regarding FMC. Also, as the authors note the impact on stillbirth rates is difficult to assess given the rarity of the outcome, but readers will find the results of the study interesting given that such a seemingly benign intervention may lead to iatrogenic co-morbidity. Some suggested revisions are listed below.

1. Introduction: The author's note the association between DFM and poor outcomes, however still birth would be the result of those pregnancy complications listed. Can the author's comment on the rates of DFM in uncomplicated pregnancies versus those with complications known to be associated with DFM?

Thank you for your comment. We agree with you. It is one of the limits present in the majority of the studies on this topic. Almost every study excluded pregnancies with a higher risk of stillbirth (for example those with fetal abnormalities), but there is no RCT that stratifies the risk of stillbirth according to other characteristics (small for gestational age fetuses, gestational diabetes, etc.).

2. Study: What are the exclusion criteria? What was the most common reason for exclusion?

We included all available randomized controlled trials in which fetal movement counting was assessed and compared with standard antenatal care. We excluded trials in which different methods of fetal movement counting were compared. This aspect is explained in the manuscript. In the included studies, the most commonly excluded pregnancies were those with fetal abnormalities (Table 1).

3. Results: In the introduction it is mentioned that a large sample size is needed evaluate the outcome of stillbirth. Did the sample size from the 5 RCTs evaluated reach the predicted sample size?

See answer above to Reviewer #3, question #6.

4. Discussion: There heterogeneity in the etiology of DFM should be discussed in the limitations. Should a prospective study stratify the groups by risk? It seems the counseling would be different in a low risk versus a high risk group.

Thank you for your comment. We agree with your position; it would be very useful to stratify the groups according to high or low risk of stillbirth. Unfortunately, currently there are no studies designed in this way. We added, ”All RCTs who mentioned it, seemed to include both low-risk and high-risk
pregnancies.”

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

Lines 48-49: Need to clarify whether the RR = .92 had p within or outside the 95% CI. Later comments (lines 124-126) imply that it was outside the 95% CI. If so, then it was simply NS, just as the all the other neonatal outcomes cited on lines 49-51. That is, there was no trend, it was simply NS from these data. The p value for the primary outcome of Perinatal death is 0.058. We have taken out the word ‘trend’ from the abstract, and everywhere else in the manuscript.

General and Table 3: Although the perinatal outcomes of death, stillbirth, neonatal death are each NS, they also are rare events and despite the large samples, one cannot generalize the NS conclusions. For example, using a control group risk of 0.54% and 200,000 in each cohort, the detectable alternative RR would be < 0.88 or > 1.12, assuming 80% power. For the less frequent outcomes of stillbirth or neonatal death, the detectable alternative RRs are even wider. That is, even with the expanded data base, these conclusions are not just NS, but under powered.
We agree. We added in the Discussion: “Therefore, despite the large sample size of our study (468,601 fetuses included), it could have been not enough to detect a small risk reduction in a rare event.”

Figs 3, 5: These simply recapitulate the findings of the study by Norman 2018, since almost all data were from that study and did not change the conclusions.
Fig 3 the primary outcome. Fig 5 can certainly be included just as supplementary material.

Figs 3, 4, 5: Two of these meta analyses include only 2 studies, so the estimation of I² to assess heterogeneity has insufficient power and the assessment of heterogeneity cannot be generalized. For the third meta analysis, there were only 3 studies, so the power was very limited to make any firm conclusion re: heterogeneity.
We agree with the statistical editor. As we stated in Discussion, “… the biggest limitation is that one study\textsuperscript{12} contributed to 82% of the total population.”

EDITOR COMMENTS:
1. Dear Vincenzo:

Thank you for submitting your meta-analysis of research on fetal movement counting. As you know, it is nearly ubiquitous in the US for women to be instructed to count their fetal movements—there is even “an app for that”! However, as you will see from the reviews, we disagree with the findings of your report. The reason is that 82% of your included participants were from a single paper, negating the ability to do a meaningful meta analysis since the other data from much smaller studies will be dwarfed by this one. You could present this as a systematic review, without a meta analysis.

As well, your primary outcome was negative and needs to be presented as such.

My conclusion from reading your paper is that the large recent paper is quite robust and begs to be confirmed—that there is not good data available on the important question of benefits of fetal movement counting. There’s just not much “there, there” other than the one big trial. (Norman JE, Heazell AEP, Rodriguez A et al. Awareness of fetal movements and care package to reduce fetal mortality (AFFIRM): a stepped 177 wedge, cluster-randomised trial. Lancet. 2018;392(10158):1629-1638)

Thank you for the feedback. We have taken out the word ‘trend’ everywhere, in the Abstract and in the text. The Abstract Conclusion, for example, is more direct, and states that: “Instructing pregnant women on fetal movement counting, compared to no such instructing, is not associated with a clear improvement in pregnancy outcomes...”.

Reviewer #2, in question #1, argues that “Is the decrease in mortality of 8% in the FMC group clinically significant? Many would argue it is.” So we have left this point as a point of further study. We have also added, as he very last phrase of the manuscript, that “Clearly, more well designed larger trials are needed.”

2. In addition to the comments from the reviewers above, you are being sent a notated PDF that contains the Editor’s specific comments. Please review and consider the comments in this file prior to submitting your revised manuscript. These comments should be included in your point-by-point response cover letter.

We have answered these points one-by-one. See below Thanks for improving our manuscript.

***The notated PDF is uploaded to this submission's record in Editorial Manager. If you cannot locate the file, contact Randi Zung and she will send it by email - rzung@greenjournal.org.*** (got it, thanks)

1. We no longer require that authors adhere to the Green Journal format with the first submission of their papers.
However, any revisions must do so. I strongly encourage you to read the instructions for authors (the general bits as well as those specific to the feature-type you are submitting). The instructions provide guidance regarding formatting, word and reference limits, authorship issues, and other things. Adherence to these requirements with your revision will avoid delays during the revision process, as well as avoid re-revisions on your part in order to comply with the formatting. Thank you for your comment. We have revised the manuscript according to the instructions for authors.

2. **We do not allow authors to describe something as non significant as in any way different between two groups--ie, no "trends".**
   Thank you for your comment. We have taken out the word ‘trend’ everywhere in the Abstract, and in the text.

3. **Counting fetal movement would not prevent mortality--its doing so, reporting the results and having some action done. One could say something like "to assess the association of fetal movement counting with perinatal mortality" as an objective.**
   Thank you for your comment. We have modified the manuscript (Abstract Objective) as you suggested.

4. **When was search begun? At inception of data base?**
   Thank you for your comment. Yes, it was. We have specified it in the manuscript in the “sources” section.

5. **In the other 2 were no instructions given? Please describe.**
   Thank you for your comment.
   Saastad et al. (ref 18) have not specified in their manuscript or in the study protocol what women had to do in case of reduced fetal movements. However, in the information brochure provided to every patient, Authors explained to contact maternity unit in case of reduced fetal movement or concern about the movement of the baby. We have added this information in table 2.
   Delaram et al. have not reported in their manuscript the information provided to women who were instructed to count fetal movement. They provided neither a clear definition of reduced fetal movement nor the instruction given to women who experienced decreased fetal movement.
   We have modified the text as “In four of five studies women in the intervention group were asked to contact the providers if they perceived decreased fetal movement, while a fifth study did not provide details.”
6. **Sentence beginning on line 49 should read: “There was no difference in perinatal outcome between groups...”**
   Thank you for your comment. We have modified the sentence as you suggested: “There was no difference in the incidence of perinatal outcome between groups.”

7. **Apgar is a woman's name, not an acronym and should not be capitalized like this.**
   Thank you for your comment. We have corrected this error in the text.

8. **Please note that effect sizes (RR, OR) within the zone of potential bias should be noted as weak. Those effect sizes in the zone of potential interest should be emphasized. (Ref: False alarms and pseudo-epidemics. The limitations of observational epidemiology. Grimes DA, Schulz KF. Ob Gyn 2012;120:920-7)**
   We have modified this text: “There were weak but significant increases in preterm delivery...”

9. **rewrite conclusion to show NO difference in primary outcomes and marginally increased rates of secondary outcomes.**
   Thank you for your comment. We have corrected conclusion underlining the absence of significant difference in perinatal outcomes: “Instructing pregnant women on fetal movement counting, compared to no such instructing, is not associated with a clear improvement in pregnancy outcomes...”

10. **emergency department or labor and delivery.**
    Thank you for your comment. We have corrected the paper as you suggested.

11. **What does "Which" refer to here--adverse perinatal outcome or increased uterine artery Doppler results? You have already articulated the association w/ adverse perinatal outcomes (line 73-74) and since ut. Artery Dopplers not done in the US very much, not clear at all what sentence staring on line 74 adds.**
    Thank you for your comment. We agree with you, the sentence was not clear enough. We have corrected it in the paper.
    Both reduction in fetal movement and abnormal uterine artery Doppler has been associated with a higher risk of stillbirth and other adverse pregnancy outcomes. Abnormal uterine artery Doppler is more common among pregnancies with decreased fetal movement, and it could represent one of the element involved in the higher rate of complications of these pregnancies. New
Moreover, compared with normal pregnancies, those characterized by reduced fetal movements have a significantly higher uterine artery PI at mid-trimester ultrasound examination and many of the adverse perinatal outcomes previously described are strongly associated with abnormal uterine artery Doppler.

12. **recommended by whom?**
Designing an ‘a-priori’ protocol, i.e. before the analysis is started, is the standard for meta-analyses, and recommended by Cochrane and others in the literature. We have simplified the phrase to say, “This review was performed according to a protocol designed a priori for systematic review.”

13. **not sure what you mean: comparing protocols and no such protocols? Do you mean RCT’s comparing women randomized to receive instructions for fetal movement counting versus NOT receiving such instructions?**
Thank you for your comment. We included all randomized controlled trials (RCT) comparing patients randomized to receive instructions for fetal movement counting versus women who received standard prenatal care, without specific information about fetal movement perception. We have explained it better in the text, “We included all randomized controlled trials (RCT) comparing patients randomized to receive instructions for fetal movement counting versus women who received standard prenatal care, without specific information about fetal movement perception.”

14. **monitor fetal movement in some fashion ....**
Thank you for your comment. We have corrected this sentence in the text.

15. **what gestational age used as lower bound for stillbirth?**
Thank you for your comment. Have added that stillbirth and neonatal deaths were recorded as defined by the studies. This is one of the limits of our review, as for example the definition of stillbirth is different in the studies included (as shown in table 1). We have added this limitation in the section “Discussion”.

16. **delete highlighted. I thought stillbirth and neonatal death were primary outcomes...why are they listed here as secondary outcomes?**
Thank you for your comment. We have deleted the highlighted. The only primary outcome measure was perinatal mortality. Stillbirth and neonatal death were secondary outcomes, each reported separately, while perinatal mortality is the sum of the two. This is standard reporting.
17. *is this included CTG AND US or CTG OR Ultrasound?*
   Thank you for your comment. It depends on the study we are considering. We have corrected the sentence in the paper. The detailed protocol used in each study in case of decreased fetal movement is reported in table 2; two of the three studies which list these details, do report doing both ultrasound and EFM assessments. New sentence, “Interventions in cases of reported decreased fetal movement varied among the studies included, but usually included electronic fetal monitoring (EFM) and ultrasound assessment of fetal wellbeing alone or in combination (Table 2).”

18. *not prior comments re: negative results (ie, no difference between groups, eliminating reference to trends.).*
   Thank you for your comment. We have modified according to your suggestions, “The incidence of perinatal death was 0.54% (1,252/229,943) in the intervention group and 0.59% (944/159,755) in the control group (RR 0.92, 95% CI 0.85-1.00; Table 3; Figure 3).”

19. *women given instructions on fetal movement counting had no significant difference in perinatal mortality compared to those who did not receive instructions.*
   Thank you for your comment. We have modified the paper according to your suggestion, “Women given instructions on fetal movement counting had no significant difference in perinatal mortality compared to those who did not receive instructions.”

20. *marginally increased rates of preterm birth......, all within the zone of potential bias.*
   Changes made as suggested, “The only significant findings were marginally increased rates in preterm birth, induction of labor, and cesarean delivery, all within the zone of potential bias.”

21. *not necessary; delete highlighted.*
   Thank you for your comment. We have deleted highlighted.

22. *Your discussion should largely focus on the poor quality, as shown by your study, of the data that underpins this nearly ubiquitous component of prenatal care.*
   Thank you for your comment. We agree with your comment and we have added this part in the text, “However, despite the poor quality of the evidence available and the necessity for future research to establish the correct approach to monitor fetal wellbeing fetal movement counting remains a nearly ubiquitous component of prenatal care.”
23. how many of currently included 5 studies were in this previous one?
   Thank you for your comment. Two of the RCT included in Cochrane meta-analysis were included also in our study. We have added three further studies. It is explained in the text.

24. Just like your study.....they found no differences.
   Thank you for your comment. Yes, despite the greater number of patients included in our study, the result did not change.

25. It's not really unclear. There is no data to support the use of FMC to prevent perinatal death. But, the data is not perfect. Please do some assessment of the paper that contributed 82% of patients. Was it a good paper? What was it's risk of bias, etc?
   We agree it's important to discuss a bit more the largest trial, by Norman et al. We added, “The largest trial was well designed and performed, but, as the authors themselves state, had some problems with compliance with the intervention, especially the ultrasound part, and found that fetal movement counting and its management as an intervention was associated with 5 fewer stillbirths per 10,000 pregnancies.”

26. delete the highlighted line
   Thank you for your comment. We have deleted the highlighted line.

27. please edit consistent w prior comments.
   Thank you for your comment. We have corrected the text as requested.

3. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
   A. OPT-IN: Yes, please publish my point-by-point response letter.
   B. OPT-OUT: No, please do not publish my point-by-point response letter.
   A. OPT-IN.
4. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.
Done

5. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration statement from the manuscript's lead author. The statement is as follows: "The lead author* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained." *The manuscript's guarantor.

If you are the lead author, please include this statement in your cover letter. If the lead author is a different person, please ask him/her to submit the signed transparency declaration to you. This document may be uploaded with your submission in Editorial Manager.
We added this statement at the beginning of this cover letter.

6. Please orient your submission to Portrait instead of Landscape.
Done.

7. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric and gynecology data definitions at https://nam01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.acog.org%2FAbout-ACOG%2FACOG-Departments%2FPatient-Safety-and-Quality-Improvement%2Frevitalize&data=02%7C01%7Cvincenzo.berg.hella%40jefferson.edu%7Ced95a9d28b824d040d0a08d73dd11ec5%7C55a89906c710436bbcc444c590cb67c4a%7C0%7C0%7C63704584068
If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter. We are familiar with reVITALize. Terms such as cesarean delivery, gestational age, gravity, parity, etc, follow reVITALize guidelines in our manuscript. Stillbirth and neonatal death were not part of reVITALize so far, to our knowledge.

8. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Review articles should not exceed 25 typed, double-spaced pages (6,250 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references. Only 19 pages, and 4,625 words all together.

9. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

* All financial support of the study must be acknowledged.
* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting). We have no acknowledgments except for authorship. These have not been previously presented.

10. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that
the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Reviews, 300 words. Please provide a word count. 292 words. We had to trim a lot of the Abstract, which was otherwise 372 words.

11. Only standard abbreviations and acronyms are allowed. A selected list is available online at [http://edmgr.ovid.com/ong/accounts/abbreviations.pdf](http://edmgr.ovid.com/ong/accounts/abbreviations.pdf). Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript. Thank you for your comment. We have removed from the text the unapproved abbreviations. We have also removed the acronym used in the précis.

12. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.
Thank you for your comment. We checked to avoid these constructions.

13. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1"). Thank you for your comment. We have revised and correct the text.
according to these instructions. We have left two decimals in Table 3 as the percentages are less than 1%, and otherwise small but important differences, such as for example on the primary outcome of Perinatal death, would be hard to understand.

14. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If on the other hand, it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

Thank you for your comment. We have revised the text according to your instructions.

15. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

Thank you for your comment. We have formatted tables as required.

16. Figures 1-5 may be resubmitted as-is with the revision.

Thank you.

17. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at https://nam01.safelinks.protection.outlook.com/?url=http%3A%2F%2Flinks.lww.com%2FLWW-ES%2FA48&amp;data=02%7C01%7Cvincenzo.berghella%40jefferson.edu%7Ced95a9d28b824d040d0a08d73dd11ec5%7C55a89906c710436bcb444c590cb67c4a%7C0%7C637045840686140704&amp;sdta=CnQnNfYZSM20jFfHv5aBWDJxufuL2aluS7PppL117U%3D&amp;reserved=0. The cost for publishing an article as open access can be found at http://edmgr.ovid.com/acd/accounts/ifauth.htm.

Please note that if your article is accepted, you will receive an email from the editorial office asking you to choose a publication route (traditional or open access). Please keep an eye out for that future email and be sure to respond to it promptly.

Thank you.

18. If you choose to revise your manuscript, please submit your revision through Editorial Manager.
Your manuscript should be uploaded in a word processing format such as Microsoft Word. Your revision's cover letter should include the following:

* A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf), and

* A point-by-point response to each of the received comments in this letter.

We have read the Instructions for Authors, and provided a point-by-point response, in this document.

Thank you and we look forward to hearing from you.

Sincerely,

Federica Bellussi, M.D.
Assistant Professor, Department of Obstetrics & Gynecology
University of Bologna, Italy

Vincenzo Berghella, M.D. (for all authors)
Professor,
Director, Division of Maternal-Fetal Medicine and MFM Fellowship Program
Thomas Jefferson University, USA