OBSTETRICS & GYNECOLOGY

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Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office: obgyn@greenjournal.org.

Date: Feb 21, 2020
To: "Hadas Ganer Herman" hadassganer@yahoo.com
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-127

RE: Manuscript Number ONG-20-127

Improving post-Cesarean mobility with personalized feedback using digital step counters - a randomized controlled trial

Dear Dr. Ganer Herman:

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 Mar 13, 2020, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

REVIEWER #1:

Overall Comments: The authors designed a randomized controlled trial addressing the improvement of mobility in high risk women undergoing cesarean section (C/S). This issue is of importance as minimizing morbidity in this patient population is of importance. The first issue that this reviewer has is how many steps in general provides a clinically important difference with respect to impact on associated morbidity and second, was the control group provided any education with respect to the importance of motility and how it can impact morbidity. If some basic information addressing this issue was not provided, there may not be equipoise between the groups. Specific comments below.

Specific Comments:

Title: Consider removal of "Improving" as the study is testing whether this will be a result of the intervention. Could consider, "The effect of personalized feedback using digital step counters on post-cesarean mobility: a randomized controlled trial

Short title: ok

Précis: consider removing "positively"

Abstract: ok

Key Words: ok

Introduction: ok

Materials and Methods: Did all subjects as a part of standardized care receive pumper hose? Were patients actually told to try to achieve 12K steps? Is there any number of steps that is known to impact morbidity? Was standardized education provided to both groups regarding the importance of ambulation?

How were subjects counselled at discharge regarding ambulation? Was written material provided? What was the definition of the modified intention to treat population?

Results: What proportion of subjects were on thrombo-prophylaxis treatment? Please note in Table 1.

Discussion: What does this difference in steps taken mean? Effect noted on physical recovery, mental recovery and satisfaction seemed modest-was statistically significant, but was it clinically significant? First sentence suggest, "In this randomized controlled trial, improved mobility was achieved among....

Where the issue of "change of policy", beginning line 258, how many subjects would be needed to see if increased mobility impacted on actual post cesarean thromboembolic events?

Tables/Figures Could consider combining Tables 1 and 2

REVIEWER #2:

The manuscript by Hadas, et al is a randomized controlled trial examining the impact of personalized feedback on the amount of ambulation in patients post-cesarean. All patients were consented and had a pedometer placed for 48 hours postoperatively (from 24 hours post-op to 72 hours). Women were then randomized to no further intervention with collection of their ambulation data at the end of the 48 hour period, or to episodes of individual feedback on their ambulation performance compared to a nomogram. The authors found that women receiving feedback on performance ambulated much further (almost double the number of steps ~6,000 steps compared to the first group's 3,000 steps). They also found that women receiving feedback had higher "physical and mental recovery scores" as well as higher satisfaction scores, without requiring a greater amount of pain medications.

This is a well-written manuscript.

Suggestions for the author:

1. The entire introduction focuses on the risk of thromboembolism in pregnancy, specifically the postpartum period and associated risk factors. However no compelling evidence is provided that extensive ambulation during the first few postoperative days decreases the overall risk of thromboembolism postpartum. This reviewer suggests the authors tone down the emphasis on thromboembolism and focus instead of the multitude of better known benefits of early ambulation in the post-operative period. These include earlier return of bowel function, attainment of post-op goals, etc - a great deal of evidence can be found in the colorectal and gynecologic oncology literature.

2. The authors should consider providing more information about why 35 women withdrew their consent and 28 patient quit prior to completion, this seems quite high for the study design.

3. The authors should acknowledge that the study is difficult to interpret as there is an intervention in each arm (the pedometer). A group with a blinded pedometer would have been more compelling. This warrants mention along with the discussion of a likely Hawthorne effect on line 250. Additionally, the benefit of ambulating ~6,000 steps versus 3,000 steps is unclear, and this should also be listed as a limitation.

REVIEWER #3:

Congratulations on completing your study and the excellent manuscript preparation. I must say that sadly, the majority of manuscripts which I review are sorely lacking with respect to the writing skills of the authors. Your paper is well written and provides good information that will ideally have wide application in using this relatively simple technology to enhance and accelerate patient activity following cesarean delivery in the high risk patient population.

A few corrections to consider:

1. page 3 line 29; use "randomized controlled" trial

2. page 7 line 107; first word should be "As"

3. page 9 line 168; the word "analysed" is misspelled

4. page 9 line 169; there is an extra word "in" that should be removed. also, "intension" is misspelled.

5. page 12 line 239; should be "Our" not "Out"

6. page 13 line 263; again, should be "Our"

STATISTICAL EDITOR'S COMMENTS:

1. Table 1: Since the groups were randomly allocated, there is no need to compare the baseline characteristics statistically. Any difference is thought to be due to random chance.

2. Table 3: Although there were no statistically significant differences in these outcomes, the study was not powered to evaluate any difference, some of the outcomes were infrequent or did not occur in either group. So, the NS results cannot be generalized.

3. Table 4: Need to clearly separate the primary from all secondary outcomes.

4. lines 149-152: Need to conform to our RCT template in abstract and need to cite the control and treatment group's mean value and the pooled SD used in the sample size/power calculation in Methods.

EDITORIAL OFFICE COMMENTS:

1. 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:
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Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.

3. Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. The statement should indicate 1) whether individual deidentified participant data (including data dictionaries) will be shared; 2) what data in particular will be shared; 3) whether additional, related documents will be available (eg, study protocol, statistical analysis plan, etc.); 4) when the data will become available and for how long; and 5) by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Responses to the five bullet points should be provided in a box at the end of the article (after the References section).

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5. It looks like there was a related prospective observational study before this study. Please be sure to disclose this in the title page your manuscript (https://doi.org/10.1080/14767058.2018.1500549).

6. 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.

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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%").

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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.

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* 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 Mar 13, 2020, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

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

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