OBSTETRICS & GYNECOLOGY

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- 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.*

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Date: Dec 08, 2021
To: "Milena M Weinstein" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-21-2125

RE: Manuscript Number ONG-21-2125

A Virtually Conducted Randomized Trial: A Digital Therapeutic Device for Urinary Incontinence

Dear Dr. Weinstein:

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).

Please be sure to address the Editor comments (see "EDITOR COMMENTS" below) in your point-by-point response.

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 Dec 29, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

1). In the abstract under conclusion please remove "… during the COVID-19 pandemi,..."
2). In the introduction I would put in a better description of the digital device. Something along the lines of a small hand-held device with a flexible tip that is inserted into the vagina and measures a change in shape or deflection of the flexible tip during a pelvic floor contraction providing feedback top the user.
3). Under materials and methods. The trial is adequately described in great detail except for the instructions and materials that the control group received. I realize the protocol has been previously published but 2 or 3 sentences about how the control group was initiated and what they received would help the reader determine if this was an active or passive control group.
4). Also under materials and methods why not have a true control group who received no instruction.
5). This study has one serious fatal flaw in that it was only 8 weeks duration. This cannot be considered true therapy for urinary incontinence as the disease is much more of a decades long or life long disease. I recognize that these types of trials are more about feasibility and patient acceptance before long term studies are done. It should be presented that way. Also how accepting where patients of the device.
6). Under discussion PASS is brought up as an outcome measure. This should be mentioned in the results section and not introduced in the discussion.

Reviewer #2:

This was a well-designed randomized controlled trial of a digital home biofeedback device for pelvic floor training compared to standard home pelvic floor muscle exercises taught via written/video instructions. Study strengths are that this study was powered with a robust sample size to see a difference in its primary outcomes (change in UDI-6 scores and 3-day bladder diary SUI episodes from baseline to 8 weeks) and demonstration of clinically meaningful differences between the intervention and control groups. Weaknesses include the short duration of follow up to 8 weeks. I commend the authors for conducting this study virtually during the pandemic, underscoring the feasibility of trials such as these. It is worthwhile

mentioning that this study was funded by the company that manufactured the device, and as such the subjects in the intervention group were provided with the intravaginal biofeedback device and given access to a 'conservative' version of the app; I am curious to know what the out of pocket cost of such a device/app services would be to the ordinary patient who wishes to use this device? Nevertheless, a robust study like this one demonstrating efficacy of this device may aid in procuring insurance coverage of such devices in the future.

Reviewer #3:

This is a randomized controlled trial comparing a biofeedback device for pelvic floor muscle training (Kegels) to regular instruction for Kegels. The study was funded by the company manufacturing the device.
1. Methods: It would be very helpful to have a figure with a picture of the device and demonstrating how it is to be used and the patient instructions. 2.5 minutes three times a day seems not very much to me, is that the standard advice?
2. Methods: Please provide more information about what the control group was doing. I don't know what you mean by "self-guided exercise progression from supine to standing position". Was this doing Kegel exercises?
3. Methods: How many of the 3 phone calls were actually answered by the study subjects to ensure they knew what they were supposed to be doing?
4. Methods: The abstract states this was a superiority trial, can you clarify that more in the methods?
5. Figure 1: What happened between week 8 and "available for analysis"?
6. Methods: Please add more regarding the rationale for a virtual trial and no physical exams?
7. Methods: Why was 8 weeks chosen as the study time period?
8. Discussion: It seems like both groups generally improved. What will be the retail cost of this device for somebody without insurance coverage? Do you anticipate insurance coverage?

STATISTICS EDITOR COMMENTS:

Abstract: Need to conform to our RCT abstract template. In particular, need to briefly state the criteria for the sample size analysis, then identify the primary outcome. Also, need to cite the primary outcome result in the format it was posited in the sample size analysis and clearly separate it from all secondary outcomes.

lines 144-150: There is no a priori basis for using a one-tailed t-test. Should have used a two-tailed test, which makes the study slightly underpowered. More importantly, what was the basis for selecting a 30% difference as the threshold? At this was 30% of what? Need to clarify.

lines 158-160: If the minimal clinically important difference in UDI-6 scores (based on scale = 100), was a difference of 11, then (Table 2), both groups achieved that difference and the difference between groups was < 7. Therefore, one could interpret the results as showing that there was a statistically significant, but clinically insignificant, difference in decreases in UDI-6 scores in the two groups.

Table 1: Since the groups were randomized, there is no need to statistically test for baseline differences. Any difference is due to random chance. Need to include units for age. Should round all %s to nearest 0.1%, not to 0.01% precision, based on denominators in the 140-300 range. Similarly, BMI should be rounded to at most 0.01 kg/m² precision.

Table 2: Need to clearly separate the primary outcome (Change in UDI-6 scores) from all other (secondary) outcomes. Also (lines 146-148) the sample size was posited on a 30% difference. Need to cite the difference in outcomes in that format. What were the differences achieved by the digital vs the control method and was that difference ≥ 30%? It does not appear that the difference between methods was ~ 10%. Need to clarify.

Fig 1: There were patients who withdrew or did not have primary outcome data. How did they compare (see Table 1) to the analyzed group?

lines 208-217, Fig 2: If one were to obtain two cohorts, based on the median agreement of device vs self reported adherence, was there a difference in UDI-6 score change for the two groups? Should be in secondary outcome analysis.

EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology have increased 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.

2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:
* Include your title page information in the main manuscript file. The title page should appear as the first page of the document. Add any previously omitted Acknowledgements (ie, meeting presentations, preprint DOIs, assistance from non-byline authors).
* Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and in the body text. For industry-sponsored studies, the Role of the Funding Source section should be included in the body text of the manuscript.
* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
* Name the IRB or Ethics Committee institution in the Methods section (if applicable).
* Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

3. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA), which must be completed by all authors. When you uploaded your manuscript, each co-author received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please check with your coauthors to confirm that they received and completed this form, and that the disclosures listed in their eCTA are included on the manuscript's title page.

4. 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.

5. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, the reasons that race/ethnicity were assessed in the study also should be described (eg, in the Methods section and/or in table footnotes). Race/ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases, missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race.

Use "Black" and "White" (capitalized) when used to refer to racial categories. The nonspecific category of "Other" is a

convenience grouping/label that should be avoided, unless it was a prespecified formal category in a database or research instrument. If you use "Other" in your study, please add detail to the manuscript to describe which patients were included in that category.

6. 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).

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 data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. 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: Original Research reports should not exceed 5,500 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, 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).
* If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."

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 limit for Original Research articles is 300 words. Please provide a word count.

11. Abstracts for all randomized, controlled trials should be structured according to the journal's standard format. The Methods section should include the primary outcome and sample size justification. The Results section should begin with the dates of enrollment to the study, a description of demographics, and the primary outcome analysis. Please review the sample abstract that is located online here: http://edmgr.ovid.com/ong/accounts/sampleabstract_RCT.pdf. Please edit your abstract as needed.

12. 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.

13. 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.

14. ACOG avoids using "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.

15. 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%").

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17. 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.

18. Please review examples of our current reference style at http://ong.editorialmanager.com (click on the Home button in the Menu bar and then "Reference Formatting Instructions" document under "Files and Resources). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.

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If the reference you are citing has been updated and replaced by a newer version, please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript.

19. Figure 1: Please check n value for those who completed week 8 in the control group.
Figure 2: okay

When you submit your revision, art saved in a digital format should accompany it. If your figure was created in Microsoft Word, Microsoft Excel, or Microsoft PowerPoint formats, please submit your original source file. Image files should not be copied and pasted into Microsoft Word or Microsoft PowerPoint.

When you submit your revision, art saved in a digital format should accompany it. Please upload each figure as a separate file to Editorial Manager (do not embed the figure in your manuscript file).

If the figures were created using a statistical program (eg, STATA, SPSS, SAS), please submit PDF or EPS files generated directly from the statistical program.

Figures should be saved as high-resolution TIFF files. The minimum requirements for resolution are 300 dpi for color or black and white photographs, and 600 dpi for images containing a photograph with text labeling or thin lines.

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If you choose to revise your manuscript, please submit your revision through Editorial Manager at http://ong.editorialmanager.com. Your manuscript should be uploaded as a Microsoft Word document. 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. Do not omit your responses to the Editorial

Office or Editors' comments.

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 Dec 29, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

John O. Schorge, MD
Deputy Editor, Gynecology

2020 IMPACT FACTOR: 7.661
2020 IMPACT FACTOR RANKING: 3rd out of 83 ob/gyn journals

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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.

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REVIEWER COMMENTS:

Reviewer #1:

1). In the abstract under conclusion please remove "… during the COVID-19 pandemi,..."

Thank you, this has been removed from line 72 of the Manuscript.

2). In the introduction I would put in a better description of the digital device. Something along the lines of a small hand-held device with a flexible tip that is inserted into the vagina and measures a change in shape or deflection of the flexible tip during a pelvic floor contraction providing feedback top the user.

Thank you for this comment. On lines 100-104 we added:

The device is composed of a small, flexible vaginal insert that takes the shape of the vagina when placed and using accelerometers, reflects the motion of the vagina when pelvic floor muscles are contracted. Data is wirelessly communicated to the users' smartphone app, and adherence to the exercise program is transmitted for cloud-based storage (Figure 1).

3). Under materials and methods. The trial is adequately described in great detail except for the instructions and materials that the control group received. I realize the protocol has been previously published but 2 or 3 sentences about how the control group was initiated and what they received would help the reader determine if this was an active or passive control group.

Thank you for this observation. Subjects were sent instructions based on the voices of PFD website, as well as a narrated slide show discussing pelvic floor muscle exercises. To clarify the nature of the information and education we have included these items in the supplemental materials, and edited the manuscript to reflect the supplement addition (lines 168-173)

Subjects in the control arm were mailed written and video instructions (on a thumb drive) regarding performance of PFMT. These were adapted from the patient advocacy group affiliated with the American Urogynecologic Society (Voices of PFD)[18] and included an exercise frequency of three times per day with self-guided exercise progression from supine to standing positions as tolerated. The information provided to the control group is included in the supplemental materials (Supplemental Appendix 3).

4). Also under materials and methods why not have a true control group who received no instruction.

Thank you for this question. When designing this study, we considered a true control group who received no instruction, but this did not accurately reflect the clinical question we were asking. Many women who embark upon a regimen of pelvic floor muscle training have been provided a modicum of education in the form of a handout regarding Kegel exercises. We decided to provide this uniformly to women as they might have been given such information had they pursued medical care for their urinary incontinence. In addition, as pelvic floor muscle exercises are recognized as effective first line care, we did not believe it ethical to offer no treatment at all for women with urinary incontinence. No changes made in the manuscript.

5). This study has one serious fatal flaw in that it was only 8 weeks duration. This cannot be considered true therapy for urinary incontinence as the disease is much more of a decades long or life long disease. I recognize that these types of trials are more about feasibility and patient acceptance before long term studies are done. It should be presented that way. Also how accepting where patients of the device.

We wholeheartedly agree that urinary incontinence is a lifelong problem for many women. We also agree that therapy may be needed longer than an initial therapeutic intervention, be that a course of pelvic floor PT or the use of a biofeedback device. We look forward to the longer-term follow up planned for this study (up to 12 months) and future opportunity to determine the best long-term course of care. The initial 8-week length of the study is based upon the results from prior studies using this device, in which significant improvement was noted at 8 weeks. We have added the following to address this concern on lines 371-373:

"Longer-term follow up is currently being conducted to better understand the durability of the treatment regimen and evaluate the need for maintenance exercises to maintain the benefits of therapy."

6). Under discussion PASS is brought up as an outcome measure. This should be mentioned in the results section and not introduced in the discussion.

Thank you for this observation. Given that this represents a post-hoc analysis, we have elected to remove it from the discussion. (pg 14)

Reviewer #2:

This was a well-designed randomized controlled trial of a digital home biofeedback device for pelvic floor training compared to standard home pelvic floor muscle exercises taught via written/video instructions. Study strengths are that this study was powered with a robust sample size to see a difference in its primary outcomes (change in UDI-6 scores and 3-day bladder diary SUI episodes from baseline to 8 weeks) and demonstration of clinically meaningful differences between the intervention and control groups. Weaknesses include the short duration of follow up to 8 weeks. I commend the authors for conducting this study virtually during the pandemic, underscoring the feasibility of trials such as these. It is worthwhile mentioning that this study was funded by the company that manufactured the device, and as such the subjects in the intervention group were provided with the intravaginal biofeedback device and given access to a 'conservative' version of the app; I am curious to know what the out of pocket cost of such a device/app services would be to the ordinary patient who wishes to use this device? Nevertheless, a robust study like this one demonstrating efficacy of this device may aid in procuring insurance coverage of such devices in the future.

Thank you! For this trial, we sought to evaluate the impact of the motion-based biofeedback device without all the other aspects of the program available to real-world users (e.g., the study version of the app did not include the patient education, videos and all of the adherence tools available to real-world users and subjects did not receive access to a personal coach), which might have clouded the results. Instead, we designed the protocol in such a way that we could attempt to isolate the impact of the device-based treatment alone. The sponsoring manufacturer, also the sponsor of this study as indicated in the manuscript, is indeed focused on obtaining insurance coverage for the device and believes the results of this study will be a key catalyst in its discussions with commercial and government payers. The current, discounted out-of-pocket cost for this prescription-only device is $650, which includes the device hardware and the full app (containing patient education, videos and adherence tools). Real-world patients are also provided access to a dedicated personal coach for the duration of use. Most real-world patients follow a recommended 12-week protocol that includes weekly check-in with their coach, personal goal setting, and accountability. Real-world patients also complete a validated symptom questionnaire each month, and the prescribing physician receives a monthly adherence and symptom change report. No changes were made to the manuscript.

Reviewer #3:

This is a randomized controlled trial comparing a biofeedback device for pelvic floor muscle training (Kegels) to regular instruction for Kegels. The study was funded by the company manufacturing the device.

1. Methods: It would be very helpful to have a figure with a picture of the device and demonstrating how it is to be used and the patient instructions. 2.5 minutes three times a day seems not very much to me, is that the standard advice?

We appreciate this question and have included a picture of the device as a figure (figure 1). The 2.5-minute regimen is standard for the device, and it is recommended to be used 2x daily when used

commercially. Given our prior research with the device, we wanted to ensure use 2x per day, and did so by asking participants to exercise 3x per day. The mean adherence was thus about 66%, or two times per day, approximating the recommended use of the device as approved. No manuscript changes

2. Methods: Please provide more information about what the control group was doing. I don't know what you mean by "self-guided exercise progression from supine to standing position". Was this doing Kegel exercises? Thank you for this question. To clarify the program, we have included the instructions received by the control group in the supplemental materials (Supplemental Appendix 3). The voices of PFD instructions direct women to perform exercises 3x daily, and to begin supine, moving to standing as tolerated. These exercises are commonly known as Kegel exercises. We added the words "*as tolerated*" for clarification on line 172.

3. Methods: How many of the 3 phone calls were actually answered by the study subjects to ensure they knew what they were supposed to be doing?

Thank you! To clarify, these phone calls with the subject were scheduled by them at their convenience. We have added this information to the manuscript (lines 247-251),
"Additionally, there were no significant differences in the number of women who participated in the three scheduled phone calls between the intervention group 86/143 (60%) and the control group 107/156 (69%), p=0.13."

4. Methods: The abstract states this was a superiority trial, can you clarify that more in the methods?

Thank you for this request. We based our decision regarding a superiority trial on the prior results of a smaller RCT, that showed positive results for the treatment arm, but was underpowered to provide potential differences. We have explained this in more detail in the statistics portion of methods (206-207).

"The prior trial, though not adequately powered, identified superior outcomes for the intervention device compared to home PFMT alone."

5. Figure 1: What happened between week 8 and "available for analysis"?

Thank you for noticing this. Those available for analysis were those who completed week 8 and provided data for analysis. Those who did not complete week 8 outcome measures were lost to follow up. We have revised the consort diagram (now Figure 2) accordingly.

6. Methods: Please add more regarding the rationale for a virtual trial and no physical exams?

Thank you for this question. We determined the need for a virtual trial in response to the research limitations imposed during the pandemic, in addition to the support in the literature for virtual care of women with urinary incontinence that emerged during the pandemic. There are several reviews underscoring the value of initiating non-surgical care even in the absence of a physical examination. Part of adapting the protocol for the virtual setting included questions (such as for pelvic organ prolapse, by using the appropriate PFDI question regarding prolapse which has been used in

epidemiologic studies) that allowed us to remotely screen for some of the details that would have been identified on physical examination. In addition to a more complete discussion of these details in the methods, we added the following text to the manuscript (lines 138-140).

"The study was conducted virtually in response to limitations on research imposed by the pandemic, in addition to literature supporting initiation of non-surgical therapy after virtual visits in the absence of physical examination. All screening and data collection was completed remotely."

7. Methods: Why was 8 weeks chosen as the study time period?

The decision to use 8 weeks as the study time period was based on prior work using the study device. Given that results in prior studies were identified at 8 weeks, and also that many regimens of supervised therapy (such as pelvic floor physical therapy) last about 8 weeks, we felt this was an adequate amount of use for evaluation. Our ongoing follow-up evaluations at 6- and 12-months will serve to evaluate the longer-term impact of the initial exercise regimen.

We have added the following text providing this information in the manuscript (lines 176-178):

"Eight weeks was chosen as the timing of the primary outcome based on prior research using the study device, as well as the authors' experience with the duration of supervised PFMT under the care of a physical therapist."

8. Discussion: It seems like both groups generally improved. What will be the retail cost of this device for somebody without insurance coverage? Do you anticipate insurance coverage?

We agree that both groups demonstrated improvement, though it is also true that on many measures, the intervention group demonstrated greater improvement. The sponsoring manufacturer is focused on obtaining broad-based insurance coverage for the device and believes the results of this study will be a key catalyst in its discussions with commercial and government payers. The current, discounted out-of-pocket cost for this prescription-only device is $650, which includes the device hardware and an updated, more robust version of the app (containing patient education, videos and adherence tools). Real world patients are also provided access to a dedicated personal coach for the duration of use. Most real-world patients follow a recommended 12-week protocol that includes weekly check-in with their coach, personal goal setting, and accountability. Real world patients also complete a validated symptom questionnaire each month, and the prescribing physician receives a monthly adherence and symptom change report. For this trial, we sought to evaluate the impact of the motion-based biofeedback device without all these other aspects of the program available to real-world users (e.g., the study version of the app did not include the patient education, videos and all of the adherence tools available to real-world users and subjects did not receive access to a personal coach), which might have clouded the results. No revisions were made to the manuscript.

STATISTICS EDITOR COMMENTS:

Abstract: Need to conform to our RCT abstract template. In particular, need to briefly state the criteria for the sample size analysis, then identify the primary outcome. Also, need to cite the primary outcome result in the format it was posited in the sample size analysis and clearly separate it from all secondary outcomes.

Thank you for this comment. We have clarified the language used to describe our sample size analysis. For the analysis, we used results from an earlier trial using the same device. The trial results favored the device, but it did not show statistical significance, and was underpowered. For this trial, we wanted to explore both a subjective primary outcome (UDI-6 score difference) and an objective primary outcome (bladder diary SUI episode change). We found that in the previous study, the UDI-6 score difference had an effect size of 0.3, and since this moderate effect size was clinically appropriate in the evaluation of a non-surgical device, we planned a properly powered study reflecting adequate sample size. The sample size needed for the bladder diary, based on the same trial was much smaller, and so the UDI-6 based sample size was used for the trial. We have amended the portion of the manuscript that discusses sample size to reflect this (lines 202-219).

"Sample size calculation was performed utilizing results from a pilot randomized trial that followed a similar protocol,[14] comparing baseline to 8-week results of the UDI-6 (subjective outcome measure) and SUI episodes on a bladder diary (objective outcome measure). The prior trial, though not adequately powered, demonstrated superior outcomes for the intervention device compared to home PFMT alone, thus a one-tailed t-test was selected. The difference in scores for the UDI-6 was -13.7 (SD = 18.7) in the treatment arm and -7.5 (SD = 21.1) in the control arm, resulting in an effect size of 0.3 (moderate effect size). Power analysis determined using a 0.3 effect size (alpha = 0.05, power = 0.8, using a one-tailed t-test), the needed sample size was 278. Allowing for an attrition rate of 20% due to the uncertainty introduced with a virtual trial format, 350 subjects were targeted for randomization. As we elected to use both a subjective and an objective primary outcome, a power analysis for the bladder diary was performed. The difference in scores for SUI episodes on a bladder diary in the same trial was 0.61 (SD=1.74) in the control arm and 1.88 (SD=2.16) in the intervention arm, with an effect size of 0.6. The sample size needed to adequately power this outcome from baseline to week 8 using alpha=0.05, and power of 0.8 was 78 subjects, which is adequately covered by the noted subjective sample size.

lines 144-150: There is no a priori basis for using a one-tailed t-test. Should have used a two-tailed test, which makes the study slightly underpowered. More importantly, what was the basis for selecting a 30% difference as the threshold? At this was 30% of what? Need to clarify.

Thank you for this question. As mentioned above, an effect size of 0.3 was selected based on a prior study using the device which represents a moderate effect size that is clinically useful in an evaluation of non-surgical approaches to the treatment of urinary incontinence. We designed this study to be a superiority study because in the prior underpowered study we saw results in both of our primary outcomes that favored the device, suggesting that superiority was the question that needed to be more definitively evaluated. Therefore, a one-tailed t-test is appropriate. No changes to the manuscript except what is detailed in the prior question regarding clarification of the power analysis.

lines 158-160: If the minimal clinically important difference in UDI-6 scores (based on scale = 100), was a difference of 11, then (Table 2), both groups achieved that difference and the difference between groups was < 7. Therefore, one could interpret the results as showing that there was a statistically significant, but clinically insignificant, difference in decreases in UDI-6 scores in the two groups.

Thank you for this question. Unfortunately, the minimum clinically important difference (MCID) used in the context of the Urogenital Distress Inventory is calculated using the full-length UDI, not the short form (UDI-6). The short form (UDI-6) is often used in research settings because it is less time-consuming for research participants. There is a "crosswalk" equation available for changing the score of the UDI-6 (a 0–100-point scale) to a full-length UDI score (0-300-point scale) which we have cited in the methods. When this is completed, the difference between the groups in our study is greater than 11 points.

Additionally, it is not clear that the difference between groups of more than 11 points is important, since the MCID is not meant to describe incremental differences between groups in multiples, but rather a baseline minimum assessing the smallest survey change resulting in significant clinical improvement. No changes to the manuscript.

Table 1: Since the groups were randomized, there is no need to statistically test for baseline differences. Any difference is due to random chance. Need to include units for age. Should round all %s to nearest 0.1%, not to 0.01% precision, based on denominators in the 140-300 range. Similarly, BMI should be rounded to at most 0.01 kg/m² precision.

Thank you for this observation. We have removed the p-values associated with the baseline differences and included the units for age. All percentages have been rounded to the nearest 0.1%, and BMI to 0.01 kg/m².

Table 2: Need to clearly separate the primary outcome (Change in UDI-6 scores) from all other (secondary) outcomes. Also (lines 146-148) the sample size was posited on a 30% difference. Need to cite the difference in outcomes in that format. What were the differences achieved by the digital vs the control method and was that difference ≥ 30%? It does not appear that the difference between methods was ~ 10%. Need to clarify.

In the study methods two primary outcomes are described. The difference in UDI-6 score between the intervention and control group was the subjective outcome, and the difference in stress urinary incontinence episodes in the bladder diary was the objective outcome. We noted these in the methods (lines 185-187), but following this review recognized that we did not include the sample size calculation for this second (objective) outcome. We have adjusted this as noted in the question above, in lines (202-219). Subjective and objective primary outcomes are described in table 2 and 3, and the results have been separated into two tables given the journal's table requirements.

Fig 1: There were patients who withdrew or did not have primary outcome data. How did they compare (see Table 1) to the analyzed group?

Thank you for this question. There were no significant demographic differences between those who

withdrew/did not have primary outcome data and those who were included in the analysis. We have added this to the manuscript (lines 247-148).

"Additionally, there were no significant baseline differences between those who were excluded from analysis and those who were included (data not shown)."

lines 208-217, Fig 2: If one were to obtain two cohorts, based on the median agreement of device vs self-reported adherence, was there a difference in UDI-6 score change for the two groups? Should be in secondary outcome analysis.

Thank you for this question. Although the opportunity to evaluate the impact of adherence is very exciting, we believe this question, and many others focused primarily on the intervention group of this study are beyond the scope of the current manuscript. We look forward to future sub-analyses that will address this question and many others regarding the contribution of adherence to successful pelvic floor muscle training as well as the impact of various patterns of adherence and even the timing of exercises. No changes to the manuscript.

EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology have increased 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**.**

2. ✓When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:
✓ Include your title page information in the main manuscript file. The title page should appear as the first page of the document. Add any previously omitted Acknowledgements (ie, meeting presentations, preprint DOIs, assistance from non-byline authors).
✓ Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and in the body text. For industry-sponsored studies, the Role of the Funding Source section should be included in the body text of the manuscript.
✓ Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
✓ Name the IRB or Ethics Committee institution in the Methods section (if applicable).
✓ Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

We have addressed these concerns

3. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA), which must be completed by all authors. When you uploaded your manuscript, each co-author received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please check with your coauthors to confirm that they received and completed this form, and that the disclosures listed in their eCTA are included on the manuscript's title page.

We have confirmed the signature of the transfer forms.

4. 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.

This has been included in the cover letter.

5. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, the reasons that race/ethnicity were assessed in the study also should be described (eg, in the Methods section and/or in table footnotes). Race/ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases, missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race.

Added to lines 156-158 (methods)

Race was included to determine whether our study population was representative of the population of women with urinary incontinence and was self-reported during the baseline assessment.

Use "Black" and "White" (capitalized) when used to refer to racial categories. The nonspecific category of "Other" is a convenience grouping/label that should be avoided, unless it was a prespecified formal category in a database or research instrument. If you use "Other" in your study, please add detail to the manuscript to describe which patients were included in that category.

We have added an explanation for “other” and “multi” in the table 1 footnotes.

6. 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).

We have provided this information in a box at the end of the article after the references

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 data definitions at https://secure-web.cisco.com/1szw1wWGAXzcH6I7DhZ8EAQ9RRK3171n0KKWnHF-Uz0jT3UcikiUh8OeIVXhDz-2hLRub2UIOjh2jswbjMlnLERwbGqpJhQPyCTohncDSNkTBBrtWOLOZm712btBsRUkeGMOMk1P1UooxpaegwaHSFnnhcM9ds7YGqjw3W_ny884124EUdKfORYTBO9dLlS2VCogd4wDAow-nHI4Sv4naPS6_3O0qkuyE2KapdhD3I878MWEIgrpPLQFJUmmIOzzZQ73hm3RTBe-qzuXTlFApPF8SSAiG7ohZgRtizT7IljrRHtBu7DqzP4vlMaiUQiG7/https%3A%2F%2Fwww.acog.org%2Fpractice-management%2Fhealth-it-and-clinical-informatics%2Frevitalize-obstetrics-data-definitions and the gynecology data definitions at https://secure-web.cisco.com/1QGSlsf6JcZKPaFg54yX8S_OBTPCBSqGL5KXCsD_oJjPEYazhDOLQV6zZXjAC3348TrwOPJOVM99l2P5lA7IX8_Mn-RLxTg0LISH6AwGtAcHbaYLlkX5kSU6QrbbLYZ5mf3tm4PRdZ6LmTky2jEc6T0Ool_qROKro-w5oTPB-9RVA1PmAxTSjAzZ4gLkfiitYFwFzDxOPR4bkXE3sv79mUAt37z8mVKTZ_zL9qQ_kv-C76y5K9kOfhTHzCYessogucjWEqh2MCm-d5nDOnJO6cQhIJepnhlt76LJjKnK3W2bCf4aa7y2Y7GZurIC41Je-/https%3A%2F%2Fwww.acog.org%2Fpractice-management%2Fhealth-it-and-clinical-informatics%2Frevitalize-gynecology-data-definitions If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

We have reviewed these definitions and believe that our manuscript is written in agreement with these definitions

8.✓ Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 5,500 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

We have not exceeded the word limit.

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.
* N/A 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).
* N/A If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."

We have noted the above guidelines and are in compliance with them.

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 limit for Original Research articles is 300 words. Please provide a word count.

The word count is 297 words. We have reviewed the abstract to ensure there is agreement between the abstract, the body of the manuscript, the tables and the figures as well as addressing critiques noted above.

11. Abstracts for all randomized, controlled trials should be structured according to the journal's standard format. The Methods section should include the primary outcome and sample size justification. The Results section should begin with the dates of enrollment to the study, a description of demographics, and the primary outcome analysis. Please review the sample abstract that is located online here: http://secure-web.cisco.com/1GP0hDZ3Fxtv2sbUKds2vz2qwYqralbkgWtTMDznLfWL3_kgM-WYpPsb60kJKZf8Xl0weZWTGlSNfSqfejXMcJuNwB3NXzYt_xEBHgmotiHN4I1AEYb8USgctdI3XL2AsSQhmjeB8IaT5vQEky52bxRbmzxa_O-PUePQyQrroBpBwRHa6vp5UKBUjQ5DYCXsj6aFD1B0YXlaWMKqd90yKTWfDblzjMKYWPw6mhstaU8v_bRL3rj_n3lTwDp8QRNBUWLhaT-RMCjR10f1TF4f8Qt-aY8vYHozSNXj-bLW23YFvN643dAcfPn-21HCpTdjq/http%3A%2F%2Fedmgr.ovid.com%2Fong%2Faccounts%2Fsampleabstract_RCT.pdf Please edit your abstract as needed.

The abstract has been revised to follow the journal format.

12. Only standard abbreviations and acronyms are allowed. A selected list is available online at http://secure-web.cisco.com/1D3_BINV3CKdGNi2-1QAHqswnpPYvCkmrnVZr1Iqll3vAlrdrEGOs5ccdrge64mefhspQkUaYBaepDPpQxm76N8y8jn5lKMh-Fcc-

Km7OF9pfv7g7yWMyZ5yEZq3IR-uF52MtigxC2lUZzOrNA4JgAhrdNIne6yOvYT3rXlDO4ZNejh6FTqJdgULeXT7rv0nouklmz2f47UkrbUtJEiYLVEHHfyTvtLHSLK4e-wdE8GTDsod3SZZsPGkbmgSbUtELQloBFfk5bY3t9UpebkJ7I8Txmo9qwXUAkINN4gGSc5VqEf7W8wbvAe9W3wQ3SI6q/http%3A%2F%2Fedmgr.ovid.com%2Fong%2Faccounts%2Fabbreviations.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.

We have reviewed our abbreviations and acronyms and believe we comply with this guidance.

13.✓ 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.

We have corrected this as needed.

14. ACOG avoids using "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.

This has been corrected.

15. 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%").

We have adjusted p values as needed and added odds ratios/relative risks between groups as needed, when possible.

16. Line 258: Your manuscript contains a priority claim. 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 it is not based on a systematic search but

only on your level of awareness, it is not a claim we permit.

We have omitted this claim (page 16).

A few publications have explored the impact of the pandemic restrictions on survey results for sexual health and urinary incontinence,[26,27] but there is a paucity of data reporting urinary incontinence specific quality of life surveys within the pandemic.

17. ✓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://secure-web.cisco.com/1JiKvvcSxhKYRyzqtbV39RwSjYTUeIDH-1rmQ5HZGbrj5v6lt4fBqQp3ZmFz6Gvpe7S42v8MOuZjV_2FdOC3GHoupkGUcfnt6tVlIAAVhPzjQBoLknk9tOYfEQZ_lRUfcxqErmHgIJNAUf7vWtSolbugue8dEJ3u1wuDVVDU-85Wsdt6XAmM4qJ8p_j5JunveV7kRCIiuZR3lQ12NgJY7qqDP8IJPwCJ4tlDopkOKUFM44p1-gpOXkVZEag7_hgg9jcOO0OazhYVMJ3Ai89K-y2ZK5Tfme4w8p17-kbSwVjXsYxP3GlI_CqwP0eBKHAH4/http%3A%2F%2Fedmgr.ovid.com%2Fong%2Faccounts%2Ftable_checklist.pdf

We have completed this checklist

18. ✓Please review examples of our current reference style at http://secure-web.cisco.com/1Vk66HNjHvfQcDbvJzGApfSvFCBeHDGTIh5hYpMp1X-wFIofgoO_vg-fx70YCNW-1-hFRP_JsX3KIdcnz914poaadWp9N3YUpKmC2t1zoWVz-TsXqrLgOnyPOM-DWnC-96TiMiH6TTy_Hd0qNCUb6I7r_a_PvfX_dc_zx3OFDN4-gnsnF_Htkc6k1HcDUT9R-ljFTG7imyc28s1rO1bc6dEID2SFz5ClTtPtkFH_IV_b5PkKzYO6ynmNAGzlNl5xOABogzY13KIHU4rEyUxHedy7mglHPbXKzr-TUHfA7YUKD09hsWshiFp3DDbCtIf6N/http%3A%2F%2Fong.editorialmanager.com (click on the Home button in the Menu bar and then "Reference Formatting Instructions" document under "Files and Resources). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.

In addition, the American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the references you are citing are still current and available. Check the Clinical Guidance page at https://secure-web.cisco.com/1biu1JpDn3rzRy6eifDXbgKAxIhG5diiBjbuIIqZs_VhEaHYda7uWp1-jYqbCdrZ3c1OFcbvXJT_7pwN3QHt2xErwQE_b-urp30azxW7sWkvccQHUlOyg8sqOYAdqKt-M5_imJ4VQ5qxa9pKvfYuRntqMTFdTSQ_zOyYgk6EPkFN1u7p1rj6vHWCxzEs7gya-kDQUg5YYun9mn8Qc6ufivn5f1i1Oc2AW22hG3tFEkytQssRw7pqlV6h-56EyVgjHC0aLz32hjfW_F988V1LE__3vPijtcrYBReS4kPvuNtZe7Q3OeM0qONKuxwG7D1E0/https%3A%2F%2Fwww.acog.org%2Fclinical (click on "Clinical Guidance" at the top). If the reference is still available on the site and isn't listed as "Withdrawn," it's still a current document.

If the reference you are citing has been updated and replaced by a newer version, please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript.

We have reviewed citations as requested

19. Figure 1: Please check n value for those who completed week 8 in the control group.

Thank you! This has been changed. Also, due to the requested addition of a picture of the device, this is now Figure 2.
Figure 2: okay (now figure 3)

When you submit your revision, art saved in a digital format should accompany it. If your figure was created in Microsoft Word, Microsoft Excel, or Microsoft PowerPoint formats, please submit your original source file. Image files should not be copied and pasted into Microsoft Word or Microsoft PowerPoint.

When you submit your revision, art saved in a digital format should accompany it. Please upload each figure as a separate file to Editorial Manager (do not embed the figure in your manuscript file).

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Figures should be saved as high-resolution TIFF files. The minimum requirements for resolution are 300 dpi for color or black and white photographs, and 600 dpi for images containing a photograph with text labeling or thin lines.

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We have added high resolution .tiff files for the art, and included the originally created figure sources

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aawK0DGVb3vqIiFEzCmg0VmBe-Pk7TUUR4nTuzEVXLlp8u87Dr5RRp_gQftHOLYr0Xe1YM20i59q6wxRJdMyr_FoAGu0Tx9js2BXBUYpE-ROu_QKzs0IwymuoToW_oeH0hcyyLBSsUXOXuVOpdd26l6HmYrdWcVoQw8rsOxoyDFNtuoOr9Gu0WJ2Yd03wZQjrFF_rhiGLVgxODQ10URw08lsmPhwo7N3Io0g8miFAUKED8FF8dse_b6s7G1/https%3A%2F%2Fwkauthorservices.editage.com%2Fopen-access%2Fhybrid.html

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