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.*

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.

Date: Feb 18, 2022
To: "Jon Fredrick Pennycuff"[redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-22-63

RE: Manuscript Number ONG-22-63

Systematic Review and Metanalysis of Commercially Available Home Pelvic Training Devices for the Treatment of Pelvic Floor Disorders

Dear Dr. Pennycuff:

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 Mar 11, 2022, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: I applaud the authors for tackling this topic. PFMT is a major component of the treatment of PFD and is beneficial, like the authors state, PFT via a trained therapist is not always possible due to various time, economic and geographic constraints and home pelvic floor therapy represents an important area of further study and development. Overall the methods are sound, however, my major concern with this study is the lack of description of which devices the included studies are evaluating. Grouping a variety of devices all of which work differently might lead to the impression of grouped efficacy, when ultimately the individual studies may show no improvement with these devices. If the authors can reconcile this by specifically describing the devices, mechanisms of action and comparing similar ones to one another I think this would greatly strengthen the manuscript.

Abstract: generally well written, please provide p-values or confidence intervals in results section

Introduction:
line 39-40: reads awkwardly, do you meant to say that PFMT has also been shown to be effective for other PFDs?

line 41-50: this can be consolidated into stating that without supervision people may not perform exercises effectively or cause worsening or new symptoms; and roughly 50% of people will not complete a PFMT regimen which may be due to forgetting to do exercises or boredom with program.

line 51-54: need to provide citations here,

Methods:
line 78-79: can you provide a list of these devices as an appendix

line 87-88: can you provide an example of such a device;

Results:
In general it would be helpful to describe what devices were tested in each study

Discussion:

line 220-229: here it would be helpful to describe exactly what devices were evaluated and how they work; comparing an biofeedback device like the Leva, to something like an insert without any feedback is a little bit like apples and oranges, and it would very much strengthen the results of this study if it was apparent that the devices truly function the same

line 230-231: i think this statement also depends on how similar/how many different devices are, if each study looked at a different device, I would be hard pressed to say that the vast majority of devices are beneficial based on a single study for each

line 256-272: this seems to be more appropriate for the results section

line 291-310: another limitation is that different devices were pooled in the same analysis, showing grouped efficacy does not mean that an individual device is helpful

Reviewer #2:

Title: Systematic Review and Metanalysis of Commercially Available Home Pelvic Training Devices for the Treatment of Pelvic Floor Disorders

Introduction Summary:
Whereas pelvic floor muscle training is well known to be effective in the conservative treatment of pelvic floor disorders, the self-administered use of home pelvic training devices has not been analyzed so far. this systematic review is showing that these commercially available home pelvic floor trainers are effective in increasing strength of pelvic floor muscles and in the treatment of pelvic floor disorders.

Novelty:
given

Methodology:
systematic review

Presentation:
very well

Hypothesis:
systematic review

Null hypothesis:
systematic review

Population:
Data sources: MEDLINE, Web of Science, ClinicalTrial.gov

Study Design:
systematic review

Inclusion Criteria:
observational cohort studies, RCTs

Exclusion Criteria:
case reports, case series, conference poster presentations, vaginal weights, cones, peripartum period were excluded

Primary outcome:
systematic review

Secondary outcomes:
systematic review

Data Collected:
relative risk ratios, pooled estimates of RRs, meta-analyses, mean difference, standard deviation of difference, overall pooled effects, descriptive statistics, 15 studies eligible for meta-analysis, study characteristics and quality
Statistics:

Results:
Large positive effect of commercially available pelvic floor training devices on pelvic floor muscle strength, reduction of 1.2 pads per day, 1.3 incontinence episodes per day, 11 grams on 24h pad test, 25.1 points reduction in UDI-6 and 14.1 points

in ICIQ7, IQOL increase by 16.8 points

Conclusions:
Commercially available home pelvic floor trainings devices are effective

Questions/comments for the Authors:

The systematic review and metanalysis of commercially available home pelvic training devices for the treatment of pelvic floor disorders is a very well written and important manuscript.

Just a minor comment for your discussion:

1. Do you think that these HPTD might be a good alternative to PFMT supervised by a physiotherapist if these therapists are not available nearby patients or other circumstances (e.g. the pandemic) make appointments impossible?

2. Does is make a difference who introduces the patients in the use of HPTD? A health care professional vs. "only" a description?

Well done, congratulations.

STATISTICAL EDITOR COMMENTS:

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

line 30, 267: Should read "whether pelvic floor ...", not "if pelvic floor..."

Fig 2: Why is the Hedge's g omitted for Segal 2016 study? Where there are entries of "p = 0.00" should change to a suitable threshold, e.g., $p < 0.001$ etc.

Fig 3, 4: Same comment re: $p < 0.00$ entries.

EDITOR 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. If you already have a PROSPERO registration number, please note it in your submitted cover letter and include it at the end of the abstract.

5. 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 6,250 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

6. Titles in Obstetrics & Gynecology are limited to 100 characters (including spaces). Do not structure the title as a declarative statement or a question. Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles. Abbreviations, jargon, trade names, formulas, and obsolete terminology also should not be used in the title. Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," or "A Systematic Review," as appropriate, in a subtitle. Otherwise, do not specify the type of manuscript in the title.

7. 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]."

8. Provide a short title of no more than 45 characters, including spaces, for use as a running foot.

9. 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 Reviews is 300 words. Please provide a word count.

10. 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.

11. 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.

12. 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.

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.

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. Line 291: 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.

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. 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.

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://www.acog.org/clinical (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.

17. Figures 1-4 may be resubmitted as-is with the revision.

18. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.

19. 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 https://wkauthorservices.editage.com/open-access/hybrid.html.

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.

If you choose open access, you will receive an Open Access Publication Charge letter from the Journal's Publisher, Wolters Kluwer, and instructions on how to submit any open access charges. The email will be from publicationservices@copyright.com with the subject line, "Please Submit Your Open Access Article Publication Charge(s)." Please complete payment of the Open Access charges within 48 hours of receipt.

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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 Mar 11, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Jason D. Wright, MD
Editor-in-Chief

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

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if you have any questions.

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April 16, 2022

University of Wisconsin School of Medicine and Public Health
Division of Female Pelvic Medicine and Reconstructive Surgery
202 S. Park St., 2E
Madison, WI 53715

RE: Comments and Revisions for Manuscript Number ONG-22-63

Dear Editor,

We would like to thank the editors and reviewers for their careful consideration of our manuscript. We have responded to each individual comment. Below each individual comment from the reviewers is in black, and our responses are in red. We have made appropriate edits to our manuscript and have included changes to the manuscript text in this letter as appropriate.

REVIEWER COMMENTS:

Reviewer #1: I applaud the authors for tackling this topic. PFMT is a major component of the treatment of PFD and is beneficial, like the authors state, PFT via a trained therapist is not always possible due to various time, economic and geographic constraints and home pelvic floor therapy represents an important area of further study and development. Overall the methods are sound, however, my major concern with this study is the lack of description of which devices the included studies are evaluating. Grouping a variety of devices all of which work differently might lead to the impression of grouped efficacy, when ultimately the individual studies may show no improvement with these devices. If the authors can reconcile this by specifically describing the devices, mechanisms of action and comparing similar ones to one another I think this would greatly strengthen the manuscript.

Thank you so much for taking the time to review our manuscript and to provide your comments. We have included, as a supplemental appendix, a list of the studies included in the systematic review, the trade name of the devices, and the type of device. We have included a description of the types of devices in the manuscript (lines 75 – 78).

While the devices have different mechanisms (i.e. biofeedback vs electrostimulation), there have not been sufficient studies comparing one modality against another to allow for metanalysis. We discuss this limitation in lines 279 – 291.

Abstract: generally well written, please provide p-values or confidence intervals in results section

We thank the reviewer for their careful consideration of our manuscript. We have included p values in the results section of the abstract.

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Introduction:
line 39-40: reads awkwardly, do you meant to say that PFMT has also been shown to be effective for other PFDs?

We have edited these lines for clarity. It now reads, “A recent Cochrane Review re-affirmed the role of PFMT in the treatment of urinary incontinence (UI) [4]. Several other studies showed that PFMT is effective for the treatment of other pelvic floor disorders such as pelvic organ prolapse, fecal incontinence, and sexual dysfunction [5-7].”

line 41-50: this can be consolidated into stating that without supervision people may not perform exercises effectively or cause worsening or new symptoms; and roughly 50% of people will not complete a PFMT regimen which may be due to forgetting to do exercises or boredom with program.

This portion of the text has been clarified for clarity.

line 51-54: need to provide citations here,

Citations have been added.

Methods:
line 78-79: can you provide a list of these devices as an appendix

We have a provided the editors with a supplemental appendix which includes the study, trade name of the device, and the modality of each device. The modality of each device is also included in Tables 2, 3, and 4.

line 87-88: can you provide an example of such a device;

We opted to not include any device trade names in the manuscript to try to remain as neutral as possible. We would be happy to include a trade name in the manuscript if the editors feel that it would be appropriate in line with the policies of the journal.

Results:
In general it would be helpful to describe what devices were tested in each study

We have provided the editors a list of studies with the name of the device and the modality of the device. Additionally, the type of device (i.e. vaginal resistance, biofeedback, electrostimulation) is included in each of the tables.

Discussion:

line 220-229: here it would be helpful to describe exactly what devices were evaluated

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[redacted]
[redacted]

and how they work; comparing an biofeedback device like the Leva, to something like an insert without any feedback is a little bit like apples and oranges, and it would very much strengthen the results of this study if it was apparent that the devices truly function the same

We have a provided the editors with a supplemental appendix which includes the study, trade name of the device, and the modality of each device. We agree that not every device is created equal. One of the goals of the manuscript was to give providers a reference to cite when patients had questions about these devices as many devices are direct to consumer. We opted to perform a pooled metanalysis instead of separate metanalysis of biofeedback devices and a metanalysis of electrostimulation devices as these two metanalyses could not be compared one against the other. We recognize this as a limitation of the study and we advocate in the manuscript for more head to head studies.

line 230-231: i think this statement also depends on how similar/how many different devices are, if each study looked at a different device, I would be hard pressed to say that the vast majority of devices are beneficial based on a single study for each

Thank you for this insightful comment. We have edited these lines in the manuscript to be more precise. The text now reads: “The majority of studies included our systematic review/metanalysis show that these devices provide benefit to patients with UI, but the added benefit compared to unsupervised- or supervised- PFMT alone is unclear.”.

line 256-272: this seems to be more appropriate for the results section

That specific text was included in the discussion section to provide context for the limitations of the available data. We specifically wanted to address that it is not known whether one type of device was more beneficial for pelvic floor disorders. The objective of the systematic review and metanalsysis was to assess the clinical efficacy of these deivces for pelvic floor disorders. We felt including the text from lines 256-272 was not in line with this objective and was better placed in the discussion to give background to the limitations of the data available.

line 291-310: another limitation is that different devices were pooled in the same analysis, showing grouped efficacy does not mean that an individual device is helpful

Please see above comment. We have edited the limitations to include your comment.

Reviewer #2:

Just a minor comment for your discussion:

1. Do you think that these HPTD might be a good alternative to PFMT supervised by a

physiotherapist if these therapists are not available nearby patients or other circumstances (e.g. the pandemic) make appointments impossible?

We thank you for your thoughtful comment. At this time there is insufficient data to say if these devices could be a good alternative to supervised PFMT which we tried to reiterate throughout the manuscript. We agree that these devices may be more logistically feasible and help with overcoming embarrassment a patient may feel about attending pelvic floor physical therapy. We feel that your comment is really a call to action about future direction for research with these devices. We have included the following text in our discussion: “Future studies on these devices should compare clinical efficacy and outcomes to patient attending supervised PFMT to understand if these devices can stand alone or serve as adjunct therapies to further reinforce supervised PFMT. In the current era of telemedicine, a better understanding of the role these devices could play in pelvic floor strengthening among patients who do not easy access to a pelvic floor physical therapist could help provide first-line treatment options to more women.”.

2. Does is make a difference who introduces the patients in the use of HPTD? A health care professional vs. "only" a description?

This is a very interesting comment. We don’t know if there would be greater impact if a healthcare provider introduces the patient to the device or if the patient find the device on her own accord. These are two very different patients that could potentially introduce bias into that type of study. I suspect pelvic floor physical therapists are the best suited to introducing patients to these devices and we have added text to introduce this concept. See text above

STATISTICAL EDITOR COMMENTS:

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

line 30, 267: Should read "whether pelvic floor ...", not "if pelvic floor..."

We thank the statistical editor for their thoughtful comments. We have corrected the text as suggestive by the statistical editor for clarity.

Fig 2: Why is the Hedge's g omitted for Segal 2016 study? Where there are entries of "p = 0.00" should change to a suitable threshold, e.g., p < 0.001 etc.

Thank you for your comments. For the analysis, the calculation was done by multiplying the Cohen D by a Hedges correction factor. The Hedges correction factor was calculated using the formula below:

$$J(\nu) = \frac{\Gamma\left(\frac{1}{2}\nu\right)}{\sqrt{\frac{\nu}{2}}\,\Gamma\left(\frac{1}{2}(\nu-1)\right)} \qquad (2a)$$

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The Segal study has a sample size of 430 so the degrees of freedom is 430-2=428. Gamma was calculated (428/2), which is infinity. The demoninator is also infinity so that is why it has a missing value for J(v). The hedge D is calculated by Cohen D*J(v). As there is a missing value of J(v), this will results in a missing value of Hedges G.

Fig 3, 4: Same comment re: p < 0.00 entries.

Figures 2, 3, and 4 have been edited to ensure the p values are shown in a more standard manner.

Sincerely,

Jon F. Pennycuff, MD, MSPH
Assistant Professor
Division of Female Pelvic Medicine and Reconstructive Surgery
Department of Obstetrics and Gynecology
University of Wisconsin School of Medicine and Public Health

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