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

Date: May 01, 2019
To: "Heidi Wendell Brown" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-534

RE: Manuscript Number ONG-19-534

'Mind Over Matter: Healthy Bowels, Healthy Bladder': A randomized incontinence group treatment trial

Dear Dr. Brown:

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

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

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by May 22, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: The objective of this trial "was to evaluate the impact of MOM on bladder and bowel incontinence symptoms and care seeking among community-dwelling older women" and is clearly stated in the introduction and abstract.

Overall this is a very well written and presented RCT on group treatment for bowel and bladder incontinence. My main concern is how the groups were divided for the analysis as outlined below. I think the readership would be interested in the idea of group teaching. If the authors were able to provide a supplement of the material covered in the classes for community women and more on-line description of the training for community members I think that would make this data more useful and able to be implemented.

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2) Along the same lines did you exclude the 44 (36%) who only had urinary incontinence from the bowel data? It looks like in the specific bowel questions you did but what about for the OR (line 320)? It seems to me that the N should be less the people who did not have bowel problems and I can't tell that this was done.

3) It is not clear to me from the reference what large trial MOM is nested within. (line 410-402) Please clarify and also consider adding the primary objective of the larger trial.

4) Figure 3: consider add p values to figure. And again it seems like the n should be less the 44 women did not have bowel incontinence which I don't think it is. If you think the women with UI only should be included please clarify how a change in stool consistency would help UI.

Reviewer #2: Abstract:
Overall concise and easy to understand with the exception of line 66. It is not clear what is meant by allocation after data collection.

Introduction:

1. This is a good overview and rationale for the study.

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Materials and methods:

3. Line 120 This clarifies the concerns addressed in the abstract. There is potential bias to begin with given all cohorts interest in participation. This is also a homogenous population in locality and race making it less generalizable.

4. Line 160 Explain the decision for female facilitators only.

5. Line 172 The use of trained observers with an objective check list on facilitators is great in assuring a consistent intervention.

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7. Line 213 Why not repeat the questionnaire at the same intervals for the fall session. The cohort would act as their own control and give a way of assessing the tool or intervention. During the wait period there may be some cross contamination if individuals are at the same community living center and discuss the intervention.

8. Line 229 The reference used for power analysis BMJ Open. 2013;3(12):e004135 found 66% vs. 11% difference in improvement. Explain in more detail how you arrived at the a priori assumption of 45% vs. 11%.

Results:

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11. Line 314 Is there more information on treatments for either urinary or fecal incontinence? A 23% response rate in the controls seems much higher than expected based upon the power calculation and prior studies. It was stated that ongoing treatments were continued if already being pursued. I would suggest listing these if available as this may be a big confounder.

12. Line 332 The difference at baseline for willingness to seek care suggest may suggest either a difference in severity and or motivation to improve. This could bias the response to the intervention.

Discussion:

13. Excellent job summarizing the existing literature and how this study fits into the larger picture of affordable healthcare delivery with clear objective and validated outcomes. The limitations of this study have been acknowledged and addressed in the discussion.

Reviewer #3: Overview: The authors randomized women to a small group intervention targeting urinary and bowel incontinence. Participants in the program showed improvement on QOL metrics as compared to controls. I would like to congratulate the authors on a well-designed study and well-written manuscript addressing this important topic.

Materials and Methods: How were participants counseled who were allocated to receive the intervention in the fall? Were they aware that they were controls for a study?
Lines 184-185: Can you please provide more information on wheat pre-existing treatments women continued during the study?

Results:
- Lines 326-327: Did you evaluate responses on the sub scales of the PFDI-20 in addition to the entire questionnaire? It would be interesting to see how responses changed (or note) on specific subscales.

STATISTICAL EDITOR'S COMMENTS:

1. lines 67-68, 218-220, 277-280: The primary outcome was improvement in UI at 4 months for treated vs control groups, but lines 277-280 seem to imply more. Namely, that both urinary and bowel incontinence were included as primary outcomes and assessed by(1) any improvement or (2) much or very much improvement. On the other hand, the

ClinicalTrials.gov site states that the assessment occurred 3 months after treatment group intervention and that both bladder and bowel incontinence were primary outcomes. Similarly, Table 2 cites both urinary and bowel incontinence and their evaluation using two metrics: "better" and "much better". If in fact there was more than 1 primary outcome or more than one metric for its assessment, then the inference threshold needs to be more strict than $p < .05$ to account for multiple hypothesis testing. Need to clarify this and consistently state and separate the primary from secondary outcomes.

2. Table 1: Need to enumerate any missing data.

3. Table 2: Besides the above comments re: primary outcome(s), the initial power/sample size estimation was based on difference in proportions, not on OR or aORs. Therefore that format (proportions, difference in proportions and CIs) should be that which is used to cite the primary outcome. ORs and aORs can be cited, but not as the primary outcome. Also, need to add a footnote citing the variables included as adjustors in the aOR modeld.

EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter, as well as subsequent author queries. 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:
1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.
2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

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

Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

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

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

5. 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 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

6. 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).

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

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

8. 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.

9. 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.

10. 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.

11. The Journal's Production Editor had the following to say about the figures in your manuscript:

"Fig 1-3: When you submit your revision, please upload these as separate files in Editorial Manager."

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.

Art that is low resolution, digitized, adapted from slides, or downloaded from the Internet may not reproduce.

12. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at http://links.lww.com/LWW-ES/A48. The cost for publishing an article as open access can be found at http://edmgr.ovid.com/acd/accounts/ifauth.htm.

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

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If you choose to revise your manuscript, please submit your revision via Editorial Manager for Obstetrics & Gynecology at http://ong.editorialmanager.com. It is essential that your cover letter list point-by-point the changes made in response to each criticism. Also, please save and submit your manuscript in a word processing format such as Microsoft Word.

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 May 22, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

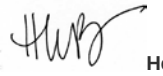
2017 IMPACT FACTOR: 4.982
2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

[redacted]

May 16, 2019
Dear Editors of *Obstetrics and Gynecology*,

I am pleased to submit the revised manuscript, **'Mind Over Matter: Healthy Bowels, Healthy Bladder': A randomized incontinence group treatment trial** for your consideration for publication in *Obstetrics & Gynecology*. It is our intent to submit solely to *Obstetrics & Gynecology* and this manuscript is not under consideration elsewhere, nor will it be submitted elsewhere until your team makes a final decision. Among 122 total patients enrolled between May 4, 2017 and the June 30, 2017, 116 provided final data.

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.

Signed by:  **Heidi W. Brown, MD**

***The manuscript's guarantor.**

This trial is registered with ClinicalTrials.gov, NCT03140852, and you can find the listing here: https://clinicaltrials.gov/ct2/show/NCT03140852. This research is not industry-sponsored. This study was approved by the University of Wisconsin Health Sciences - Minimal Risk Institutional Review Board. We followed the CONSORT guidelines for reporting randomized controlled trials and have also uploaded the CONSORT checklist with page numbers specified where required information is provided.

The following pages include the reviewers' suggestions and our authors' responses, indicated with track changes both in this letter and in the uploaded revised manuscript. As a dissemination and implementation researcher and urogynecologist, I would be thrilled to share the results of this trial with the *Obstetrics and Gynecology* readership; I look forward to your decision and am happy to provide any additional information.

Thank you very much,

Heidi W. Brown, MD MAS FACOG
[redacted]

[redacted]

RE: Manuscript Number ONG-19-534

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Thank you very much your careful and thoughtful review and kind words about our work. I added some additional information about the workshop (lines 148-157) and facilitator training (lines 175-181). We work closely with a dissemination agency whose role is to train, certify, license, and monitor community organizations that implement evidence-based programs to make sure that the programs being implemented in communities maintain fidelity with the evidence-based versions of the programs, and I have added the link in the section describing the facilitator training so that community members who happen to read this paper can visit our dissemination agency's website to learn more.

Minor:

1) The introduction made me think this was a trial for women with dual incontinence (particularly lines 101-102, & 108-10) and then it seems the trial is for women with either (bowel or urinary incontinence) or both (line 181-182). How do you think this impacts the primary outcome since urinary incontinence was not a requirement? I recognize only 1 participant had bowel incontinence alone, but then why was UI not an inclusion criteria?

Thank you very much for this comment. The Green Journal does not allow the use of "and/or," which makes this point difficult to clarify. In line 119 I changed phrasing to read "reduce symptoms of urinary, bowel incontinence, or both." I removed the word "and" from line 133 so that it reads "women who have or want to prevent bladder or bowel symptoms." I made the word "or" bold and italicized in line 198 to emphasize that women did not need to have both UI and bowel incontinence.

As far as how it impacts our primary outcome, it's a great question, and an example of how research and the real world can differ. While we always planned to examine impact on both urinary and bowel symptoms, in our grant application, we thought that we would have two primary outcomes: UI improvement for most women (with isolated UI or dual incontinence), and FI improvement for women with isolated FI. We had specified that we would use improvement in urinary symptoms as the ***primary*** outcome for women with urinary symptoms alone or urinary and bowel symptoms, since the intervention on which this one was based had already been proven to improve urinary symptoms. We planned to use improvement in bowel symptoms as the ***primary*** outcome for women who had isolated bowel symptoms, because we anticipated that more than a single woman with isolated bowel symptoms would enroll in the trial, but we were wrong. As such, we were not adequately powered to assess that outcome as primary for that participant. In retrospect, we could have just made UI an inclusion criterion and improvement in UI the primary outcome for all participants from the start, but we hoped to provide a solution that would reach women with isolated bowel incontinence too, and we didn't want to exclude that group from this trial.

Based on comments from the statistical reviewer, we revised our description of our primary outcome and analyses in the Methods section, lines 288-304.

2) Along the same lines did you exclude the 44 (36%) who only had urinary incontinence from the bowel data? It looks like in the specific bowel questions you did but what about for the OR (line 320)? It seems to me that the N should be less the people who did not have bowel problems and I can't tell that this was done.

Thank you for the comment. We did not exclude the women who only had urinary incontinence from the bowel data because all participants received an intervention that could impact both bowel and bladder continence. Many women with UI have constipation, which makes urinary incontinence worse by minimizing the space the bladder has to store urine, and so all women in MOM are advised to make fiber modifications to optimize stool consistency – regardless of whether they have bowel incontinence specifically.

Based on your comment, I have also presented comparison of rates of any and very much improvement in UI among the subset of women with any urinary incontinence (excluding isolated bowel incontinence) and any and very much improvement in bowel incontinence among the subset of women with any bowel incontinence (excluding isolated urinary incontinence). See addition to methods section lines 312-317 and modified table 2.

3) It is not clear to me from the reference what large trial MOM is nested within. (line 410-402) Please clarify and also consider adding the primary objective of the larger trial.

Thank you very much for the comment. In a prior version of this paper we explained more about hybrid effectiveness-implementation trials in our introduction, but eliminated that explanation from this version, so I can see how its mention here in the discussion section is confusing! Please see modifications to lines 450-452. Hybrid effectiveness-implementation studies focus on both effectiveness and implementation outcomes; type 1 is primary effectiveness, type 3 is primary implementation, and type 2 is equal weighting of effectiveness and implementation outcomes. This trial was mostly about effectiveness, but we collected another year of data from communities (not workshop participants) about whether they adopted MOM outside of the research context, whether they maintained the program by offering more than once following the RCT, whether it was implemented with fidelity, and information about barriers to and facilitators of adoption, maintenance, and implementation of the program. We initially tried to present those data in this manuscript too, but it was too long and therefore we opted to divide into two manuscripts, one focusing on effectiveness and another focusing on implementation (which we plan to submit to a health promotion / public health journal, not a clinical journal).

4) Figure 3: consider add p values to figure. And again it seems like the n should be less the 44 women did not have bowel incontinence which I don't think it is. If you think the women with UI only should be included please clarify how a change in stool consistency would help UI.

Thank you for the suggestion. I added p-values to the figure legend and the text in the results section (lines 381-384) but I struggled to add them to the figure itself without it becoming too cluttered. Many women with UI have constipation, which makes urinary incontinence worse by minimizing the space the bladder has to store urine, and so all women in

MOM are advised to make fiber modifications to optimize stool consistency – regardless of whether they have bowel incontinence specifically. Some language to explaining this phenomenon was added above in the description of the workshop based on your prior comments.

Reviewer #2: Abstract:
Overall concise and easy to understand with the exception of line 66. It is not clear what is meant by allocation after data collection.

Thank you very much for the comments. What we are trying to communicate is that those allocated to the control group completed the same intervention as those allocated to the treatment group, but they did so after all follow-up data collection was completed. The abstract word limit is 300, which makes it hard to say what we need to say there. Perhaps the revision I made to lines 65-66 will be more clear.

Introduction:

1. This is a good overview and rationale for the study.

Thank you very much.

2. Line 94 I would recommend expanding on the targeted type of incontinence. OAB, stress fecal incontinence gas, stool or liquids. The reference # 6 JAMA : the journal of the American Medical Association. 2010;303(21):2172-2181 looks at different types of intervention for each.
Thank you very much for the suggestion. At the suggestion of another reviewer, we expanded upon the description of the intervention in lines 148-157 and provided some information about tailoring of behavior changes that MOM participants may make based on their symptoms. The workshop provides information about different types of incontinence and specific behavior changes that may improve these different types of incontinence, but participants are not required to disclose their symptoms (though many choose to do so).

Materials and methods:

3. Line 120 This clarifies the concerns addressed in the abstract. There is potential bias to begin with given all cohorts interest in participation. This is also a homogenous population in locality and race making it less generalizable.

Thank you for the comment; I am glad it is more clear here. The point about potential bias given all cohorts interest in participation is excellent and I added a statement acknowledging that in lines 437-440. It is indeed a common problem with clinical trials and limits generalizability to persons who want to participate, not to all persons with the condition of interest. (In fact, we have just completed another study looking at women who do NOT opt to participate in continence promotion, which reflect the majority of women!). We completely agree with weakness re: homogenous population and have addressed it in line 425.

4. Line 160 Explain the decision for female facilitators only.

Thank you for the comment; we have added the rationale to lines 167-170 – during feasibility testing community members expressed discomfort with the presence of a male team member and requested that this program for women be facilitated by women exclusively. (There have also been lots of requests from male community members for a program targeting bladder and bowel symptoms for men, and that's one of our areas for potential future pilot-testing and adaptation; we have not collected data about whether men would have a preference for facilitator).

5. Line 172 The use of trained observers with an objective check list on facilitators is great in assuring a consistent intervention.

Thank you very much. We modeled our fidelity checklist off an existing one for another evidence-based program and have since revised it to include not just adherence to the facilitator script and time requirements, but also adherence to the concepts of adult education and facilitation skills taught in the training, so that it truly evaluates whether the program is delivered with fidelity to underpinning concepts.

6. Line 180 Explain the definition of independent living. Given the inclusion requirement of > 50 with an avg. age of 75 there may be quite a range of independence which may impact ability to adhere to many of the interventions.

Excellent point. The question we used for screening was worded: "Do you live independently? By this, I mean living on your own or with someone else, but not needing assistance with daily activities," and I have added that definition to lines 196-197. There were a number of participants who used ambulatory assistive devices but all were able to dress and toilet independently.

7. Line 213 Why not repeat the questionnaire at the same intervals for the fall session. The cohort would act as their own control and give a way of assessing the tool or intervention. During the wait period there may be some cross contamination if individuals are at the same community living center and discuss the intervention.

I know – it seems crazy not to ask the fall participants about the impact of the workshop on their symptoms, doesn't it!? Many women in the control group asked us that same question. We didn't have the money in the budget to pay for additional questionnaire completion.

In retrospect, I wish we had surveyed ***both groups*** again three months after the control group did their workshop, because then we would also have collected longer term data for the treatment group, but as noted above, we were limited by our budget. Next time, for sure!

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We did explicitly discuss with participants the importance of not sharing the information learned in the workshop with their friends until the trial was over, and there certainly could have been communication between treatment and controls. None of the study sites were living centers specifically, though participants could have lived in the same senior independent living communities.

We were reassured that we saw significant differences between treatment and control groups, because cross-contamination would have made us less likely to see those differences. We were also reassured by the stable and low number of women doing pelvic floor muscle exercises in the control group (8%, 9%, 8% throughout the study), suggesting that their friends in the treatment group didn't share class materials with them.

Additional lines have been added to this effect in the discussion section (Lines 427-435)

8. Line 229 The reference used for power analysis BMJ Open. 2013;3(12):e004135 found 66% vs. 11% difference in improvement. Explain in more detail how you arrived at the a priori assumption of 45% vs. 11%.
In the Tannenbaum study, participants were asked about their improvement by telephone, rather than by self-reported questionnaire, so we thought it was possible that some participants reported more improvement than they actually experienced. In our preliminary feasibility testing with 55 women in 5 communities, 45% of participants reported that their urinary incontinence was much better 3 months after completing MOM, which is why we used the more conservative estimate of 45% for proportion of improvement in the treatment group. We took the 11% from Tannenbaum's study because our preliminary testing did not include controls. Please see revised language to clarify in methods, lines 240-244.

Results:

9. Line 303-304 This is a high participation and high completion rate.

Thank you. Participants were recruited by trusted members of their community, so I think that is part of the reason why participation was high. We mailed a research literacy infographic to participants with the final questionnaire, showing how our study results would change if some people did not respond, and potentially leading us to make conclusions that were not true, and I think that helped our completion rate (along with the financial incentive, of course!)

10. Table 1 Is there demographics information on the type of incontinence and parity?
We did not collect information about parity. We did collect information on stress and urge urinary incontinence, on leakage of solid stool, liquid stool, and gas, and fecal urgency, through the PFDI-20, and the prevalence rates of those conditions in our sample have been added to table 1 based on your comment.

11. Line 314 Is there more information on treatments for either urinary or fecal incontinence? A 23% response rate in the controls seems much higher than expected based upon the power calculation and prior studies. It was stated that ongoing treatments were continued if already being pursued. I would suggest listing these if available as this may be a big confounder.

We did not collect information about specific ongoing treatments in either group. (sentence added in line 202). Participants were not eligible if they had started new treatment for either urinary or bowel incontinence in the three months prior to enrollment, and were asked not to initiate new treatments (other than the MOM workshop) during the study duration. There are often natural changes in fluid and fiber intake and exercise during the summer months, which may have contributed to improvement in both groups. I added a sentence about this in the discussion section (lines 434-435).

12. Line 332 The difference at baseline for willingness to seek care ~~suggest~~ may suggest either a difference in severity and or motivation to improve. This could bias the response to the intervention.

Thank you for your comment. While more participants in the treatment group had previously sought care for urinary incontinence, there were no statistically significant differences at baseline between treatment and control groups on any validated measures of urinary or bowel incontinence severity. We added a sentence to this effect in the discussion, lines 440-443.
Discussion:

13. Excellent job summarizing the existing literature and how this study fits into the larger picture of affordable healthcare delivery with clear objective and validated outcomes. The limitations of this study have been acknowledged and addressed in the discussion.

Thank you very much – we did add some additional discussion of limitations based on your astute comments above.

Reviewer #3: Overview: The authors randomized women to a small group intervention targeting urinary and bowel incontinence. Participants in the program showed improvement on QOL metrics as compared to controls. I would like to congratulate the authors on a well-designed study and well-written manuscript addressing this important topic.

Thank you very much!

Materials and Methods: How were participants counseled who were allocated to receive the intervention in the fall? Were they aware that they were controls for a study?

Excellent question. The telephone script for initial screening with participants described participation and allocation as follows

"I would like to tell you a bit more about the workshop. *Mind Over Matter* is a free four-week workshop to help people remain independent, increase confidence, and improve issues with bowel and bladder control. It's important because more than half of women over age 50 have issues with bladder or bowel control. These issues can impact our physical and emotional well-being, make us stop participating in activities we enjoy, and

even increase our risk of falls. Participants in Mind Over Matter learn what they can do to take control of their bladder and bowel health, including exercises, what to eat and drink, how medication can contribute to these issues, and much more. Each session is about two hours long and meets every other week. The same group of 8 to 15 women will be in each of the three sessions. There will be workshops held in [city] this spring and fall. Do you have any questions so far? Does this workshop sound like something you would be interested in attending?

If yes: Excellent! Right now we are offering participation in the workshop as part of participation in a research study. In addition to attending the workshop sessions, we would also ask you to complete three survey questionnaires. Half of the volunteers for the study will complete the workshop in the spring and will complete the survey questionnaires AFTER the workshop. The other half of the volunteers will complete the workshop in the fall and will complete the survey questionnaires BEFORE the workshop. Because it is a research study, volunteers do not get to choose which workshop they attend: the study randomly assigns volunteers to do the workshop in EITHER the spring of the fall, so we ask that all volunteers be available to attend the workshop at either time. You will be notified of your assignment within two weeks of starting the study. Participation in the study is voluntary."

Here is the description from the informed consent document:
"If you decide to participate in this research you will be asked to do the following:

- Take part in the Mind over Matter: Healthy Bowels, Healthy Bladder workshop. This includes:
  - Attending the series of three sessions lasting about two hours each that will be held every other week in your community. The workshop includes lectures, group activities, personal goal setting, and some simple exercises to help control bowels and bladder.
  - You will be asked to practice the exercises at home.
  - You will be asked to set some personal goals and keep track of your progress at home.
- Be randomly assigned to attend the workshop in either the spring or the fall. This means that you cannot choose whether you attend the workshop in the spring or the fall. The study coordinator will tell you which group you have been assigned to, and you will be expected to attend the workshop in that group. "

When we gave presentations and talked about the study both during recruitment and when sharing results with communities, we said, "No one wants to be in the control group and not get the workshop, so the women in the control group still get/got to do the workshop, but they will do it/did it AFTER they finish(ed) the research questionnaires."

Lines 184-185: Can you please provide more information on wheat pre-existing treatments women continued during the study?

Another reviewer wanted more information about this too. We did not collect information about specific ongoing treatments in either group. (see additional sentence in line 202). Participants were not eligible if they had started new treatment for either urinary or bowel incontinence in the three months prior to enrollment, and were asked not to initiate new treatments (other than the MOM workshop) during the study duration. There were participants who volunteered that they were taking a bladder or bowel medication, and they were allowed to enroll as long as the medication had not been started or dose changed in the last three months. There was a participant using interstim who had not changed her settings in more than three months but I don't remember whether the device was on or not.

Results:
- Lines 326-327: Did you evaluate responses on the sub scales of the PFDI-20 in addition to the entire questionnaire? It would be interesting to see how responses changed (or note) on specific subscales.

We ran these analyses based on your request and revised the results section lines 364-369:
POPDI6 change (SD) -3.74 (15.61) in control vs -4.79 (16.09) in treatment, p=.72.
CRADI8 change (SD) -.92 (14.33) in control vs -6.12 (15.72) in treatment, p=.068.
UDI6 change (SD) -4.96 (12.49) in control vs -11.90 (18.79) in treatment, p=.02.

STATISTICAL EDITOR'S COMMENTS:

1. lines 67-68, 218-220, 277-280: The primary outcome was improvement in UI at 4 months for treated vs control groups, but lines 277-280 seem to imply more. Namely, that both urinary and bowel incontinence were included as primary outcomes and assessed by (1) any improvement or (2) much or very much improvement. On the other hand, the ClinicalTrials.gov site states that the assessment occurred 3 months after treatment group intervention and that both bladder and bowel incontinence were primary outcomes. Similarly, Table 2 cites both urinary and bowel incontinence and their evaluation using two metrics: "better" and "much better". If in fact there was more than 1 primary outcome or more than one metric for its assessment, then the inference threshold needs to be more strict than $p < .05$ to account for multiple hypothesis testing. Need to clarify this and consistently state and separate the primary from secondary outcomes.

Thank you very much for your careful review and insightful comments. Our study enrolled participants with urinary incontinence, bowel incontinence, and both, and so we did not think we could use a single primary outcome for all participants (because of the group not having a single unifying diagnosis). Thus, our plan was to have two primary outcomes: ANY UI improvement for women with UI (either isolated UI or dual incontinence), and ANY bowel incontinence improvement for women with isolated bowel incontinence. We knew the majority of participants would not have isolated bowel incontinence, so our power calculation was based on projected UI symptom improvement. We ended up with a single primary outcome in the trial because only one participant in our trial had isolated bowel incontinence (we had not anticipated that number being so low).

We always planned to look at the impact of the intervention on both UI and bowel incontinence and to look at both any improvement and much or very much improvement, not because we were testing multiple primary hypotheses, but rather because clinicians would be interested not just in any improvement in UI, but also in much/very much improvement specifically, and similar outcomes in bowel incontinence, but everything other than any improvement in UI according to the PGI-I was planned as a secondary outcome.

I have revised the methods and results sections of the manuscript to be more clear – see lines 288 through 304 in methods section; lines 342-350 in results section; table 2 modifications. I have also included the p-values in table 2, all of which are <.0125, which would be the most conservative Bonferroni correction if we assumed 4 potential primary outcomes (any and much improvement in urinary and bowel incontinence).

2. Table 1: Need to enumerate any missing data.

Thank you for the comment. N's have been added throughout the table. I hope it is not too busy.

3. Table 2: Besides the above comments re: primary outcome(s), the initial power/sample size estimation was based on difference in proportions, not on OR or aORs. Therefore that format (proportions, difference in proportions and CIs) should be that which is used to cite the primary outcome. ORs and aORs can be cited, but not as the primary outcome. Also, need to add a footnote citing the variables included as adjustors in the aOR modeld.

Thank you very much. Table 2 has been revised and footnote added.

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Added.

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

Not problematic.

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Noted.