Author's response to reviews

Title: Yoga for Managing Knee Osteoarthritis in Older Women: A Pilot Randomized Controlled Trial

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Dear Dr. Rowles,

Thank you and the reviewers for the valuable comments that helped strengthen the manuscript. This letter is written to give a point-by-point response to the concerns. The comments from the reviewers along with how they are addressed in the revised manuscript are listed below.

Reviewer 1

1. I found the analyses which combined the intervention and wait list control groups confusing. I think that the authors must determine what their primary goal of the pilot is and then analyze their data accordingly.

The specific aims of the study are clarified on page 6. The specific aims are to: 1) Examine the differences in pain, stiffness, physical function of the lower extremities (LE), body mass index (BMI), quality of sleep (QOS), and quality of life (QOL) between the treatment and wait-list control groups, 2) evaluate the effects of yoga on OA-related outcomes over time, 3) assess our ability to recruit and retain participants, and 4) measure adherence during yoga sessions and home practice. Comparing data between the intervention and wait-list control is for meeting specific aim #1. Combining data from both treatment and wait-list controls into one group (both post-treatment) with baseline variables as the covariate, a repeated measures ANCOVA model, using mixed models, was employed to meet specific aim #2 which is to assess changes over time. This analysis approach has a lower type I error and higher power than if only data
from the intervention group were used.

2. Much of the discussion tries to explain/justify why results for certain outcomes were inconclusive. This seems at odds with the pilot/feasibility nature of the study, as it was not powered to detect statistically significant or clinically important differences for outcomes of interest. Consider revising so that discussion more logically follows from the study aims as presented in the introduction.

The discussion section has been revised on pages 16 - 18 to reflect the pilot nature of the study. The paragraphs that explain the inconclusive outcomes are removed. It is now logically flows from the study aims.

3. Please clarify what the time points are. I am still confused about whether the “12 weeks follow-up” is 20 weeks after baseline or 12 weeks after baseline. Please clarify.

The four time points are now clarified as “baseline, 4 weeks, 8 weeks and 20 weeks.” The time point of 20 weeks is used to replace the previous “12 weeks” throughout the manuscript.

4. P8, 2nd line: “furthered” should be “further”

It is corrected. Sorry for the oversight.

5. P9, Please explain how the study quality was monitored by the research mentors.

The following sentence “Progress reports including participant recruitment, retention/attrition with reasons for dropout from the study, and a summary of adverse events were sent to DSMB members for independent reviews. Quarterly meetings were held between the research mentors and the PI to review the study progress.” is added to page 9 to clarify how the study quality was monitored.

6. P10, line 1: What unit of distance does the “8” refer to? Is it 8 meters? Please write it out to reduce confusion.

The unit of distance is 8 foot. It is now written out on page 10.

7. Results, p12. The authors state that “among the 180 potential participants contacted …”, however, in their methods, they explained that multiple methods were used to recruit participants, including hanging flyers. Therefore, it does not seem possible to know the denominator, meaning the number of potential participants who were contacted. It may be more clear to report the number that were mailed letters, while specifying (if this is known) what number of those screened learned about the study from the mailed letter rather than other means. If the recruitment source for the people who contacted the study is not known, consider revising the first sentence of the results.

The original numbers included in version 2 are those who were contacted directly. Because it was impossible to know the exact number of potential
participants who were contacted, the first sentence on page 12 as the CONSORT diagram are revised.

8. P14. The authors describe Table 1 as showing differences, but it means and SD/ranges are shown.

The means and 95% CI for each measure by groups are presented. The differences are implicit as the differences between these two numbers. The Table has been relabeled to clarify this.

9. P14, 1st full paragraph. Please reference Table 2.

Table 2 is referenced for the results on secondary outcomes (page 14).

10. P15, last paragraph. Please explain what numbers are presented in parentheses. Ranges?
Yes, they are ranges. The term is included to clarify the numbers.

Reviewer 2

1. The authors have clarified that the 12-week follow-up assessment comes 12 weeks after completion of the 8-week intervention, or 20 weeks after baseline in the cover letter. However, the design section still does not clearly spell this out for readers. The flowchart does not chronologically show the wait-period followed by the 2nd group receiving yoga. Please use separate sentences to describe the assessments for each group, and do not say 4 weeks, 8 weeks, and 12-weeks after the intervention. This implies that all 3 of those time frames occur after the intervention.

The four time points are now clarified as “baseline, 4 weeks, 8 weeks and 20 weeks” in the design section as well as throughout the manuscript. The diagram has been revised to chronologically show the wait-period followed by the second group receiving yoga.

2. The second sentence of the design section seems missing something “The treatment group received an 8-week Hatha yoga intervention involving group and home-based exercise sessions and the wait list control group.”

The revised sentence is now read “The treatment group received an 8-week Hatha yoga intervention involving group and home-based exercise sessions. The wait-list control group received the same yoga intervention after the treatment group completed the program at the end of 8 weeks.”

3. Why not use one of the design names mentioned in the cover letter? Instead it says wait list and that they eventually got yoga. Please state the intent to use crossover effects and combine the data.

We greatly appreciate the reviewer’s recommendations. It is our understanding, however, that because participants in the treatment group were not asked to stop practicing yoga that this was not a true crossover design; the treatment group did not become a control group. Wait-list control is the closest term we found that
describes the intention of the study. Once the control group has been assessed, they also receive the intervention.

Associate Editor

1. The authors have not adequately addressed Reviewer 3’s concerns. I would suggest asking them to strictly adhere to CONSORT guidelines for a RCT mentioning on which page of the manuscript a particular change was made.

The title and the manuscript is aligned with CONSORT guidelines. See attached CONSORT checklist with specific page numbers included.

We hope these revisions are satisfactory to the reviewers and that this manuscript is suitable for publication in BMC Complementary and Alternative Medicine. Thank you for reviewing this manuscript. We look forward to receiving your comments.

Sincerely,

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