Author's response to reviews

Title: Protocol for a randomized controlled study of Iyengar yoga for youth with irritable bowel syndrome

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Dear Editors,

Thank you for the reviewer comments regarding our recent manuscript referenced above. We have considered the reviewer comments and have modified the manuscript according. Please find below a point-by-point response to each concern.

1. The randomization process has been described in greater detail (please see page 15 of the manuscript). Thank you for providing the very helpful references regarding appropriate randomization procedures for clinical trials. These articles were very useful in refining the detail for our procedures.

2. Thank you for identifying the incorrect power calculation. This has been corrected and the appropriate section of the manuscript has been re-written (pg 29). We have now calculated the study power based on a likely medium effect size (based on our previous pilot work with patients with rheumatoid arthritis). Using a range of correlations between baseline and follow-up scores (.1 to .5) we selected the midpoint value (47 total patients). A 20% attrition rate gave us a value of 60 total patients. The G*Power program automatically adjusted the standard deviation for the correlation values.

3. The statistical plan has been simplified and the section related to considerations of distributions has been removed. The analysis plan has been changed to involve ANCOVA rather than ANOVA.

4. The reference to imputation for missing data has been removed.

5. The sentence describing the first set of analyses comparing the baseline yoga and control group scores has been removed.

6. The study protocol is part of a junior career development award (K01) granted to the principal investigator to explore potential outcomes and mechanisms of yoga for youth with IBS. Given the preliminary and exploratory nature of the study a large number of variables were selected in the hope that this study will guide future larger-scale trials with more targeted outcomes.

Best regards,

Subhadra Evans, Ph.D.