Author’s response to reviews

Title: A Technology-Assisted Health Coaching Intervention vs. Enhanced Usual Care for Primary Care-Based Obesity Treatment: A Randomized Controlled Trial

Authors:

Clare Viglione (clare.viglione@bmc.org)
Dylaney Bouwman (dylaney.bouwman@nyumc.org)
Nadera Rahman (nerahman@gmail.com)
Yixin Fang (yixin.fang@njit.edu)
Jeannette Beasley (jeannette.beasley@nyumc.org)
Scott Sherman (scott.sherman@va.gov)
Xavier Pi-Sunyer (fxp1@cumc.columbia.edu)
Judith Wylie-Rosett (judith.wylie-rosett@einstein.yu.edu)
Craig Tenner (craig.tenner@va.gov)
Melanie Jay (melanie.jay@nyumc.org)

Version: 1 Date: 31 Oct 2018

Author’s response to reviews:

Dear Mr. James Mockridge and the Editorial Board for BMC Obesity,

We are delighted to submit our revisions to our manuscript entitled “A Technology-Assisted Health Coaching Intervention vs. Enhanced Usual Care for Primary Care-Based Obesity Treatment: A Randomized Controlled Trial.” We appreciate the editor and reviewer comments and the manuscript is now stronger. We have attempted to address each comment below point by point. Thank you for the opportunity to publish our work in BMC Obesity.

Sincerely,

Melanie Jay, MD MS
Editor Comments:

This paper offers a contribution to the evidence base but needs to be reframed to some degree in light of the reviewers comments. In particular, there is an over-emphasis on weight loss data for a feasibility study. While these results may provide some information about trends and effect sizes, the study was not designed to evaluate effectiveness of weight loss and the interpretation of this needs to be removed from the abstract. Instead, as noted by reviewer 2, the abstract needs to be reframed to support the overall aims and objectives related to feasibility and this should be weaved throughout the paper.

We agree with this feedback. We removed discussion about weight outcomes from the conclusion and emphasized that this was a feasibility study (See Abstract lines 31-32 and 43-47). We also addressed reviewer 2’s comments and weaved the study aims throughout the manuscript.

Reviewer reports:

Douglas Evans (Reviewer 1): This is an interesting and well written paper that describes a technology-assisted obesity treatment coaching intervention. The study is well conceived, methods and results clearly presented, and conclusions well supported.

Thank you for this positive feedback.

1. Introduction is very brief and doesn't provide much background. Authors should add details on theoretical basis for the intervention, any prior work that led to the current study, and support from the relevant published literature.

We have added more information about how our intervention was based on the 5As counseling framework and gave more detail and citations about our intervention development (see Background, lines 95-102). In the discussion, we provide information about other primary care-based studies and how the GEM intervention is novel yet builds upon these studies (See Discussion, lines 364-373).

2. The authors note that the intervention was based on formative research but provide no details. Say a bit more about it, and if available provide citations to published results of the formative work.

We gave more detail and references of our formative work (Background, lines 95-102).

3. Discussion says nothing about implications and future research suggested by this study. What should be done next? Authors need to enhance discussion of what this research tells us about the interventions strategy and what future studies should be done.
This was originally buried in the conclusions section. Based on this feedback, we strengthened our description of how we plan to use findings from this pilot to improve the GEM intervention and to inform future research by listing the challenges we identified and how we are going address them in the future. We put this earlier in the discussion and incorporated more detail (See Discussion, Lines 373-435).

Cynthia Thomson (Reviewer 2):

1. Abstract -suggests a revision to assure the content of the abstract clearly defines the study objectives, related outcomes, results and conclusions as described in the paper. For exp the purpose was to determine the feasibility AND acceptance; Results- what is "high quality counseling" and wasn't it described as health coaching? ; results: "tended to lose more weight" is an interpretation and does not belong in results, rather simply stating the specific weight change differences.; Completing coach calls was associated with weight loss -but only in GEM group - please qualify; what were the results re: increasing participation in MOVE!? Conclusion: should add that process evaluation resulted in several changes in program methods/strategies.-

Thank you for these very specific and helpful suggestions. We rewrote much of the abstract to incorporate this feedback and highlight that this is a feasibility study.

2. Throughout the manuscript, the authors should be consistent in reporting aims (line 77-82), methods of each aim, results of each aim, discuss each aim and pull together a conclusion that encompasses all study aims.

We are now more consistent with stating our aims in the background and have restructured our methods and results by each aim. Moreover, the discussion now explicitly discusses the study aims.

3. Line 103 - seems a large number of patients attend a single MOVE! session - were those that only attended 1 session of MOVE! also excluded? please qualify. –

We clarified in the text that participants were excluded if they attended more than three MOVE! sessions within the preceding twelve months (See Recruitment and Participants, Line 126).

4. Describe the coaches in more detail - how many undergraduate? graduate? what programs? what was the attrition rate for coaches? on average, how many coaches did a patient work with? a table may be helpful in this regard.

We added information regarding education level and sex but unfortunately no further demographic data were collected (See Health Coaches, Lines 162-167). We also described that the health coaches typically worked for 10-15 hours per week for 1 year. While we do not have
attrition rates, we report mean number of health coaches per participant in the GEM intervention arm of the study.

5. Consider providing fidelity checklist to add clarity regarding components of coaching that were routinely evaluated.

We have added our fidelity checklist as Appendix 1.

6. In discussion- expand on the high rates of patient declining to participate and "not reached" - seems very high, do you think this introduced selection bias related to those who did participate?

We have provided more detail about our recruitment processes and their impact on the study. For example, those that elected to participate may have been more motivated or more engaged in VA care than the average Veteran population, which could limit generalizability (See Limitations, Lines 434-435).

7. In terms of coaching calls completed - was completion associated with any of your demographic or clinical data/ variables presented in the table?

Based on this feedback, we explored associations and differences between demographic and clinical data and call completion using Spearman’s correlations and Wilcoxon Rank Sum Tests (See Methods, Lines 264-267; Results, Lines 307-312; and the additional Table 3).

8. Discussion - qualify the feasibility - if such a large number do not even start the program is it feasible in addressing the obesity therapeutic needs of your population?

We understand why this is a concern, but we believe that it is still very important to try to engage patients in intensive behavioral interventions given that they have the highest level of evidence for lifestyle-based treatment. Further, we specifically reached patients who had not attended MOVE! in the past year. In the discussion, we describe our plans to increase attendance including encouraging attendance to outside programs if they cannot attend MOVE! (see Discussion, Lines 417-421) which may better address the needs of the population.

9. Discuss the clinical relevance (or lack thereof) of a 1 kg weight loss - unlikely to change metabolic indices but if it promotes enrollment in MOVE! that would be enough - the enrollment rate was 2-fold higher in GEM vs EUC participants- but overall only 6 enrolled.

We have addressed the clinical significance of weight loss found in this study and further elaborated on how we plan to increase the magnitude of weight loss in the next iteration of GEM (see Discussion, Lines 357-362).
10. Several times in document data are stated as singular rather than plural (data is versus data are), please correct.

Thank you for pointing out this problem—we have corrected it throughout the manuscript.

Sincerely,

Melanie Jay, MD, MS

Associate Professor
Departments of Medicine and Population Health
Co-Director, NYU Langone Comprehensive Program on Obesity
Director of Research Collaboration and Mentorship
New York University School of Medicine