Reviewer’s report

Title: Effects of a Parallel Arm Randomized Controlled Weight Loss Pilot Study on Biological and Psychosocial Parameters of Overweight and Obese Breast Cancer Survivors

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Reviewer: Linda Larkey

Reviewer's report:

This is a well-designed study with exceptional selections for rationale and biomarker measures. Well-written.

Well explained rationale of the biomarker selection. In the abstract as well as in the discussion, explain the selection of biomarkers and association with cancer recurrence (maybe in the abstract, simply note "cancer recurrence related" biomarkers?). Also note more in the introduction what the association of these factors might be related to weight loss/exercise/diet---why might one expect these to change?

Intro: needs explanation for the choice of the two interventions, why choose these to compare as intervention/control? Needs more review of the literature. What is the history of programs designed to look at these sorts of intervention, and evidence for effect on weight, both short term and long term, then extend to the added purpose of the pilot study in gaining insight into biomarkers associated with recurrence.

Method.

Very nice touch to choose a 1000-calorie deficit dietary plan based on baseline biometrics/diet of individuals at baseline.

Readers don't "see" that the CR diet is a feeding intervention with prepared meals until methods section! We need to see this earlier (even mention in abstract), as this is a critical factor. And we don't see that not only is there a prescription for exercise, but that they need to show up to DO the exercise 2 x week/4 weeks, while the control only gets counseling. These are interesting and important design features, but need to be addressed earlier in the rationale/intro, relating these choices to past studies and evidence for gaining adherence.

Why choose 18 weeks for fitness assessment?
also justify why 1 month past treatment for eligibility—discuss in limitations that some parameters such as inflammation, stress, qol may still be impacted from coming off of treatment so recently and influence the trajectory of recovery (even if in both groups, may be adding noise)

Consort flowchart should be included. Blinding information for study staff, participants?

Results/discussion

Needs a separate limitations section to discuss the small sample, imbalance at baseline in BMI, and other factors that didn't get assessed (behavioral, adherence, etc) that might provide more clues to changes. Definitely address the lack of diurnal cortisol analysis (a much better predictor of recurrence and/or death)—it is fine to note that the choice for 24 hour urine sample was fine for pilot, but a bigger question would be to look at a full sampling of 2-3 days of diurnal cortisol collection.

Finally--- if there is limited adherence (dietary intake or exercise) measures, it is difficult to determine if the results are due to adherence or to the specific type of intervention. (only the CR group kept activity logs, even in the last 6 week follow-up?). This is as much a behavioral study (what works to get women to make these dietary and exercise changes? Do women in CR eat other than what given?) as it is an outcome study. Yes, as a pilot study, it isn't expected that all of these things are measured, but this will be important in the discussion section.

Make more of the "pilot' nature of the study and what can be done next (including some of the issues mentioned in above notes). Citations for choices of study design, including the choices around eliminating some of the outliers to re-analyze certain outcomes, would be helpful. (agree with the choices, but it helps to justify your conclusions if you have references that confirm these strategies for analysis in pilot studies). THEN the results need to have a shift in conclusions.

Also make more of the potential of this study to help unpack the links between exercise/nutrition and biomarkers of recurrence. Associating the potential mechanisms related to associations we have seen in the longitudinal data (e.g., more exercise, less recurrence) is a strength of this study, even as a pilot. It never hurts to say what is needed next...not just "further research" but specifically what might be more rigorously tested.

Wonderful potential contribution to the literature.

Level of interest
Please indicate how interesting you found the manuscript:

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Quality of written English
Please indicate the quality of language in the manuscript:
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