Reviewer's report

Title: Feasibility study for a randomized controlled trial on patient education plus acupuncture for relieving breast cancer-related fatigue

Version: 1 Date: 5 November 2010

Reviewer: Suzanna Zick

Reviewer's report:

Please view all of these suggestions as major compulsory revisions

Overall,
I like that the researchers tried a multi-modal approach to treating CRF. This is novel and if done/reported correctly could potentially inform future treatment for CRF and help in the evolution of the methodology for conducting multi-model therapies. However, his manuscripts focus on recruitment strategies is uninformative and unoriginal. These are not new methods or problems encountered in clinical trials (in complementary medicine or outside of it) and would not be of particular interest either to researchers or clinicians. I would suggest the authors focus on the effect on BFI via the multi-model aspects of their study. However, a considerable rewrite would need to occur to make this an acceptable manuscript. Some changes are detailed below but the authors would also have to recast their paper based on the above comments.

Please, check tenses and change appropriately throughout the manuscript.

INTRODUCTION

The section “The first is that common recruitment strategies, even those with successful track records, may perform poorly in new situations.[9] Complementary and alternative medicine (CAM) trials also have recruitment problems.[10] Accordingly, our first objective is to report how our informal experimentation with a variety of recruiting methods helped us develop a tailored recruitment strategy that appears effective for a larger-scale study.” Is very wordy and could be edited and condensed to something like, "Our first objective is to investigate how a variety of recruiting methods helped us to develop a tailored recruitment strategy that appears effective for a larger-scale study.”

The last sentence of the introduction is confusing and does not follow with the information just presented.

Methods

Why were other potential causes of fatigue such as hypothyroidism, hepatitis, etc. not part of your exclusion criteria? Also, please indicate if the participants needed to be apparently free of active cancer at time of enrollment into the study.
Please, add the following to your methods section

Intervention: Considerably more detail should be added about the life style changes in exercise, nutrition, etc. that was offered to participants. For instance, exact details of what type of exercise, how frequently should the exercise be performed, how the exercise was explained to participants etc. This should be extended to each of the parts of the intervention. Readers would also need to know if these lifestyle changes were individualized or standardized. Also, indicate how these interventions were monitored, i.e., logs, pedometers for foot counts.

While appropriate to reference the study from which you derived your acupuncture points you still need to briefly list what they are, how long a treatment was, and how often you gave treatments and any modifications. I would refer to the STRICTA guidelines for reporting acupressure studies to guide this section.

Outcome: As determining effective recruitment strategies is a large part of the study they should be added to the outcome section. How was a particular strategy measured and what was used to determine a method was successful?

What about adverse events or compliance as outcomes? Where these not assessed or recorded? If not why? And if yes, please include in the manuscript.

Statistical Methods: Please, add how descriptive statistics were handled, i.e. baseline characteristics. Also, add how the statistics for the recruitment strategy where handled as well as for adverse events and compliance, if appropriate.

Please, add a power analysis. I am aware that this is a pilot study but some justification for sample size is needed.

Human Subjects: Please add “all participants provided written informed consent”

RESULTS

Recruitment Strategies: This section has to be reported in much better detail as this is emphasized as the main objective of the manuscript. May I suggest that you report the screened to on-study ratio for each method, i.e., we had to screen 10 women at the BC clinic to gain one person enrolled on the study (1:10 ratio). Also the length of time to do each of these strategies would be helpful.

Baseline Demographics: Please add in the 6th person who withdrew from the study to treatment group.

Please, indicate if true, that there was no statistically significant difference between either group based on sociodemographic or clinical indications instead of “There was no evidence that the randomization procedure failed to provide for a fair comparison between treatment and control in the relief of BFI-measured CRF.”

Add the mean age with standard deviation and some basic information about race/ethnicity and leave the rest to the table.

Fatigue Reports: Please indicate what the mean difference between groups in BFI from baseline to end of study along with standard deviation (not error).
Report the p-value from your model from the treatment variable and round off to the second decimal place.

Discussion: Please rewrite the discussion to focus on the clinical trial and not the recruitment strategy. Compare and contrast your results to other studies using, exercise and acupuncture/acupressure. How is your study better, worse ect. Add how well participants followed study suggestions in the treatment group. What are your studies limitations. Also, be specific as to what would be the next logical study(s) would entail.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

'I declare that I have no competing interests'