Reviewer's report

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

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Reviewer: Jun Mao

Reviewer's report:

This study describes a feasibility trial of multi-modal intervention (including self-care and acupuncture) to improve breast cancer related fatigue. The intervention is well-thought out and is very innovative. The effect size of the intervention to address cancer-related fatigue seems to be clinically relevant and has strong potential. The writing of the paper can be strengthened in a number of ways. Major weaknesses were

1) Incomplete summary/discussion of existing acupuncture/acupressure trials for fatigue literature (Molassiotis 2007, Balk J 2009, Mao JJ 2009, Zick 2011 just name a few that I have seen on Pubmed). It is helpful to put your findings in the context what we know and don’t know about acupuncture for cancer related fatigue and point out the unique contribution of your research which is bringing counseling on self-care.

2) Although the recruitment of 16 patients in 15 months did not suggest the feasibility to recruit for a larger trial in a timely fashion, the author’s effort in trying multiple methods to enhance recruitment is a contribution to the research in this area. I think the data can be better displayed by creating a diagram specifically on recruitment that is aside from the consort diagram. The diagram should provide pathways on how many enrolled patients are achieved through each method over what duration of time. My gut feeling from reading the paper is that the waiting room recruitment yielded a few subjects in a relatively short time. However, with the current way of displaying the data, the authors did not justify why they reached that conclusion.

3) Please discuss limitations of the study

Specific comments:

Title may benefit from more descriptive one (e.g. rather than multimodal): “Integration of self-care education and acupuncture”

Abstract: Please change the results as, “Compared with usual care control, intervention is associated with greater reduction in BFI, effect, 95% confidence interval, and p-value”. The way the author described the results was not typical for a trial reporting.

Abstract conclusions: The conclusion should be changed to “The promising effect
of this intervention warrants the conduct of a larger randomized controlled trial to confirm the findings and effective recruitment strategy is essential for its successful execution”. By reading the results, I am not quite convinced the feasibility of recruitment has been established by this study.

Introduction: Need to review briefly the existing therapies including acupuncture to build a stage why your intervention has some empirical support and plausibility and you are fulfilling an important gap in research.

Methods:
Need to give references for BFI, HADS in second paragraph when they first appear. Need to spell out HADS when first used.

Interventions: It is uncertain that the self-care session were in-person or by phone, individual vs. group. If individual, why not having one acupuncturist provide both? The acupuncture protocol should be clarified as fixed or allow individual variations.

Since this is a phase II trial, should describe the justification for sample size a priori even if one fails to recruit target the sample size.

Results:
Recruitment: It is a bit confusing and number does not add up. Based on my reading, 21 from previous study, 51 from PI letter, 1 from news letter, 3 from flyer, 5 from oncology clinic, total of 81; however, the consort shows only 40 patients. Please clarify. It is probably helpful to use a diagram to show exactly which recruitment methods actually resulted in patients enrolling (over what time).

Outcomes: It is a bit strange to see a phase II trial without any secondary outcomes. It may strengthen the paper if the authors have some relevant secondary outcomes (sleep, pain, QOL) also showing some degree of improvement. This is not critical to the publication of this paper; however, it will strength the paper substantially.

Discussion:
Based on the data presented by authors, there is no evidence that waiting room recruitment is more effective. Using a diagram with more clear description may help making it clear to readers.

Please discuss how your work is similar or differ from other acupuncture/acupressure/counseling alone trials.

Any study, even well-done phase III trials have limitations. Please think carefully and discuss the limitations of your work.

In your conclusion, please add that thoughtful and proactive recruitment methods are needed for successful conduct of the larger trial.
Level of interest: An article of importance in its field

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