Reviewers report

Title: Effects of an 18-week exercise programme started early during breast cancer treatment: a randomised controlled trial in daily clinical practice

Version: 1 Date: 10 March 2015

Reviewer: Siobhan Phillips

Reviewers report:

Overview
This study describes an 18 week physical activity intervention that was implemented in clinical practice. The intervention was associated with a lower increase in fatigue and increased fitness and muscle strength in compared to usual care during active treatment for breast cancer. Overall, the study is well-written, but could be strengthened by providing more details regarding the intervention, specifying the clinical significance of these findings and providing some additional thoughts on future directions.

MINOR REVISIONS

Abstract
1. Please add a statement to the conclusions that discusses the implications of the findings from this study.

Background
1. Please rephrase the statistics on fatigue to state that up to 70% and up to 30% as the estimates of prevalence vary widely in this population.
2. Sentence starting with “The intervention…” I think you are missing the word “and” between diagnosis and was.

Methods
Setting and Participants
1. What is meant by stage M0? Please clarify.
2. Were there any inclusionary/exclusionary criteria relevant to current physical activity levels? Please comment on this within the text.
3. How exactly were women recruited? It seems that the sample may be a bit healthier and more active than would be expected. Could this have something to do with how potential participants were identified?
4. The last sentence is worded somewhat awkwardly.
5. Did recruitment vary across sites? Were participants similar?

Intervention
1. Please add “social” in between Banduras and cognitive.
2. How exactly were the preference and fitness levels determined to individualize the training?
3. Please specify the length of the total interval session and each individual intervals and what is meant by “low ventilatory threshold”. Was this monitored during exercise?
4. How was training intensity re-evaluated every 4 weeks?
5. Was the activity prescribed outside of the program aerobic activity? How was adherence to this portion of the intervention monitored?
6. What is meant by “exercise programmes offered routinely”? Please clarify.

Sample Size and Statistical Analysis
1. In the statement starting with “With the current number of participants…,” please specify the n.
2. How was adherence to the 210 minutes of exercise assessed?
3. Did the authors consider a sub-analyses examining those who were adherent in the intervention group compared to those who did meet or exceed the PA recommendations for the control group to provide greater insight into what the potential effects would be in comparison to those who were not doing the same amount of exercise?

Outcome Measures
1. Was aerobic capacity based on volitional termination of the exercise test?
2. Please provide information on the reliability/validity of the PA measure used.

Results
1. Were all participants lost to follow-up excluded from analyses? If yes, please specify.
2. Please present data on adherence to the intervention protocol prior to the other results.
3. Did the intervention participants engage in significantly more activity post-intervention than pre-intervention? Did they engage in more activity post-intervention/at follow-up than control participants?

Discussion
1. Why is physical fatigue most likely to be influenced by exercise? Please explain.
2. Mechanisms paragraph: What about psychosocial mechanisms? There are some studies which suggest PA may decrease fatigue through its effects on self-efficacy and depression.

MAJOR REVISIONS

Methods
Intervention
1. Given that this intervention was implemented in practice, I would have liked more information on the flow of participants through the intervention (from recruitment to enrollment) to understand how participants were identified and who was involved (from a staffing point) in the trial.
2. How was fidelity to the intervention measured across sites?

Results
2. Aside from statistical significance, were the differences observed clinically meaningful even if they were/were not statistically meaningful?

Discussion
1. I think a major limitation of this study is the fact that it seems as though the participants included may have been the ones that needed the program given their high pre-diagnosis activity levels.
2. Some other potential weakness of this study are: a) the lack of an objective PA measure so all findings are based on self-report and b) the use of a submax exercise test which may be less sensitive to change, especially in women who are already pretty active and likely relatively fit. Additionally, it is hard to tell what type of activity (since it is combined aerobic and resistance training) might be driving some of the results.
3. Please provide some future directions in the context of this study.

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests.