**Reviewer’s report**

**Title:** Randomized clinical trial to evaluate the effect of a supervised exercise training program on readmissions in patients with myocardial ischemia: a study protocol

**Version:** 1  **Date:** 26 December 2012

**Reviewer:** Clinton Brawner

**Reviewer’s report:**

The manuscript by Santaularia et al. describes the methods for a randomized, controlled trial. This study will enroll patients with a hospitalization associated with a primary diagnosis of a myocardial infarction (MI). The intervention is an exercise program. The primary outcome is admission for a recurrent MI. The authors sufficiently identify how this study addresses a gap in our current knowledge on this topic. This continues to be an important area for clinical research.

**Major revisions/considerations**

1. The power calculations appear to be for a chi-square analysis. If this is true, this study may not be adequately powered to show a 13% difference in event rates between groups based on a log-rank test. How will deaths and loss to follow-up be handled in this analysis? How many covariates might be included in the analysis based on the event rates?

2. The primary outcome stated under “Assessment of outcomes” seems to conflict with the study purpose. Listed here is “hospital admission for cardiovascular disease”. It seems like should be specific to MI. Is the primary outcome time to first MI hospitalization?

3. Absent in the study design is how the investigators will address issues of cross-over. Will this be an intent-to-treat analysis? Cross-over will affect the study’s internal validity. In a randomized trial of exercise training in patients with chronic heart failure (N = 2331), ~30% of the patients in the exercise group achieved the protocol target of 90 min of exercise per week and 22-28% of the non-exercise control group reported exercise during the first 3 mo (O’Connor et al., Efficacy and safety of exercise training in patients with chronic heart failure. HF-ACTION randomized controlled trial. JAMA. 2009;301(14):1439-1450).

**Minor revisions/considerations**

1. Although a purpose statement is provided, the paper would be improved by providing a clearly defined hypothesis near the end of the introduction.

2. A randomized controlled trial is appropriate to address the study’s purpose (e.g., does exercise training reduce the recurrence of MI in patients who are...
post-MI). It is interesting that the randomization occurs before visit 1. Is it possible that some patients will drop out before visit 1 due to dissatisfaction with their group assignment?

3. Follow-up visits are shown out to 12 mo post-discharge. This will be just 10.5 mo after completion of the 10 wk exercise program. The time interval over which the primary outcome will be assessed is not clear. Is the maximum duration of follow-up 12 mo after discharge?

4. The authors suggest that cardiac rehabilitation is an international standard of practice for secondary prevention in patients with heart disease. With this in mind, it is interesting that a study that withholds cardiac rehabilitation was approved by their institutional review board. There may be regional issues that make this study acceptable. It would benefit the reader if the authors briefly discussed this.

5. What criteria will be used for MI diagnosis?

6. Myocardial “ischemia” appears to be used interchangeably with “infarction”. I believe the authors mean to use “myocardial infarction”.

7. Specific exclusions are limited or vague. Are there specific exclusions, such as ability to ambulate?

8. Please provide more information relative to the exercise test. Is this a maximal exercise test? What instructions (e.g., medications) are provided to patients in preparation for this test?

9. How long after the exercise test do patients start the exercise program? Do patients continue in the exercise program until they complete 30 visits or does their participation end after 10 wks?

10. Are there methods, such as heart rate monitors, to ensure that patients are exercising at their prescribed intensity?

11. Isometric exercise (muscle contractions with no change in muscle fiber length) is listed as part of the exercise program. This is not typical. Is the intention resistance training through isotonic exercise (muscle contractions with constant load and change in muscle fiber length)?

12. Confounding variables: This appears to be a list of descriptive variables of interest rather than confounders.

13. Table 1- Is visit 0 discharge?

14. Figure 1- What is the “baseline assessment”? I thought baseline data is collected at visit 1.

Level of interest: An article of limited interest

Quality of written English: Needs some language corrections before being
Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

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