Author’s response to reviews

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

Authors:

Nuria Santaularia MSc (nsantaul@althaia.cat)
Josefina Caminal MD PhD (Josefina.caminal@uab.cat)
Anna Arnau MSc (aarnau@althaia.cat)
Montserrat Perramon BSc (mperramon@althaia.cat)
Jesus Montesinos MD (jmontesinos@althaia.cat)
Jaume Trapé PhD (jtrape@althaia.cat)
Montserrat Abenoza MD (mabenoza@althaia.cat)
Pere Guiteras MD PhD (pguiteras@althaia.cat)
Tiny Jaarsma RN PhD (tjaarsma@liu.se)

Version: 3 Date: 20 March 2013

Author’s response to reviews:

Manresa, March 20 2013

Revision decided for MS:5334526728297987, " Randomized clinical trial to evaluate the effect of a supervised exercise training program on readmissions in patients with myocardial ischemia: a study protocol”.

Dear Dr. Shipley,

Thank you for your review of our manuscript ”Randomized clinical trial to evaluate the effect of a supervised exercise training program on readmissions in patients with myocardial ischemia: a study protocol”. We are very pleased to hear that the reviewer considers the manuscript to be relevant to BMC Cardiovascular Disorders. His comments have been very helpful and have enabled us to make important improvements.

The changes we have made are listed below in our response to the reviewer’s comments.

We hope very much that you will now consider the paper suitable for publication.

Sincerely,

Núria Santaularia
Department of Rehabilitation.
Althaia Xarxa Assistencial Universitària de Manresa, Manresa, Barcelona, Spain.
PhD student, physiotherapist. Department of Medicine. Universitat Autònoma de
• The revised manuscript by Santaularia et al., “Randomized clinical trial to evaluate the effect of a supervised exercise training program on readmissions in patients with myocardial ischemia: a study protocol” shows meaningful improvement over the original submission. For the most part, they have addressed the reviewer’s comments.

- Thank you. We very much appreciate the reviewer’s positive comments and we have introduced the modifications suggested (see response to specific comments).

Major revisions/considerations

1. It remains unclear whether the primary hypothesis will be tested using Chi-square (Statistical Issues, paragraph 1) or a time-to-event analysis (Statistical Issues, paragraph 5). Time-to-event would be a stronger methodology.

- We agree with the reviewer that it may not yet be clear enough how we intend to perform the statistical analysis to test the main objective.

- Sample size was calculated assuming a decrease in the percentage of patients readmitted for cardiac disease in the intervention group. Therefore, the main aim of our study should be analysed through a two-tailed #2 test for two independent samples. Additionally, and although we know we do not have enough power, we would like to test (in an exploratory way) whether there is any trend between the groups in the time to first hospital readmission for cardiac disease. To clarify this point we have modified the second paragraph of Statistical analysis section by adding:

- Page 17 - Statistical analysis - 2nd paragraph

“Percentage of patients readmitted for cardiac disease will be analysed through a two-tailed #2 test for two independent samples, and time to first hospital readmission for cardiac disease will be analysed as time to event with Kaplan-Meier estimation and Cox proportional regression models.”

2. Discussion, paragraph 2, last sentence: The fact that there currently is no cardiac rehabilitation program within this hospital and possibly the region is an important point. This addresses the ethical concern - mentioned in the original
review - that a standard of care is being withheld.

- We thank the reviewer for this comment. We apologize that this part was not clear.

Cardiac rehabilitation is an international standard of practice for secondary prevention in patients with heart disease. In our hospital, we apply a cardiac rehabilitation program. In this clinical trial, we have added “the supervised exercise training program” in the intervention group as an additional component of our cardiac rehabilitation program. In accordance with international guidelines, both groups in the study will be recommended to take unsupervised physical activity. Additionally, for the purposes of the study the intervention group will be provided with a supervised outpatient exercise training program.

- We have made some changes in the discussion part to clarify this point (page 19): “Thus, this clinical trial may encourage the systematic implementation of supervised exercise training program on cardiac rehabilitation programs in our environment.”, “…there is no central unit that organizes secondary prevention and supervised exercise training programs for cardiac patients”.

Minor revisions/considerations

1. Statistical Issues, paragraphs 1 & 5: Consider including “cardiac” with each mention of hospital readmission.

- Thank you for this comment. We apologize for the lack of clarity.

- We have now added the term “cardiac” with each mention of hospital readmission in paragraphs 1 & 5.

2. Limitations, paragraph 1, sentence 2: This meaning is not clear. I think you mean it may be difficult to enroll patients who do not live near the hospital; therefore the final cohort may not be representative of the entire catchment area.

- One of the characteristics of our reference region (which is largely rural) is the geographical dispersion. Distance from our hospital could be a reason for non-participation, which could affect the external validity of our study. In the reasons for non-participation, we will explicitly record “Difficulty in getting to the hospital”.

- To clarify this point, we have modified the last sentence of Limitations section.

- Page 18 – Limitations

“Another limitation may be the difficulty of including patients due to the large size of the catchment area and its mainly rural nature. This may restrict the inclusion process due to the distance and transport problems, and may limit the external validity.”

3. I don’t see where Figure 1 is called out within the text.
Thank you for this comment. We have added “see figure 1” on page 12.

Level of interest: An article of limited interest

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.