Author's response to reviews

Title: Do supervised weekly exercise programs maintain functional exercise capacity & quality of life, twelve months after pulmonary rehabilitation in COPD?

Authors:

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Author's response to reviews: see over
The Managing Editor
BMC Pulmonary Medicine

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Dear Managing Editor,

Thank you for your response regarding the study protocol titled:

MS: 7726972171261997
Do supervised weekly exercise programs maintain functional exercise capacity & quality of life, twelve months after pulmonary rehabilitation in COPD: RCT
Lissa M Spencer, Jennifer A Alison and Zoe J McKeough

In response to the reviewer’s comments:

1. Comment: “I note that the study is not blinded. Obviously this may be difficult but it should be possible to blind the assessor.”

Response: While we are aware that blinding would be optimal for the study design, this is not possible in the study situation. The two major outcome measures will be exercise capacity and quality of life. We will institute the following procedures to minimize any possibility of assessor bias: 1) all exercise tests for the assessment of exercise capacity will be performed twice at each measurement point with the better result used for analysis; 2) the six-minute walk test will have standardised instructions and standardised encouragement, which will be read from a printed sheet; 3) the incremental shuttle walk test and the endurance shuttle walk test will be externally paced, and the standard instructions for these tests will be delivered by pre-recorded tapes with no further encouragement provided by the assessor throughout the tests (Singh et al, 1992, Revill et al, 1999); 4) the St George Respiratory Questionnaire (for the measurement of quality of life) will be self-administered and will be scored by a computer program. The standardisation of all these procedures will limit assessor bias. The trial is already registered with the Australian Clinical Trials Registry (ACTR 1260500678695) as an unblinded study.


2. Comment: “The control group is not strictly non-intervention. The patients will be given home exercise programmes and telephone support. This may lessen the sensitivity of the study.”

Response: The reviewer suggests that the control group is not strictly a non-intervention group. It is true that the control group will be given advice on home exercise however, this is in keeping with standard practice following Australian pulmonary rehabilitation programmes and therefore we have called this a “control group” to which we will compare the intervention group of supervised exercise. If exercise advice for the “control group” does have an effect we recognise that this may reduce the effect size of the study. However, based on the results of the study by Ries et al (2003) we do not anticipate exercise capacity will be maintained at post pulmonary rehabilitation levels in this group at 12 months follow-up.

The reviewer also mentions that the control group will receive telephone support. This is not strictly correct as the subjects will not be telephoned by the investigators, but will be given the option to ring the investigators if necessary, as would be the case in any research trial. As telephoning the researchers is not considered part of the intervention, we have removed this from the Methods to avoid confusion (page 7, line 2).


3. Comment: “I think there are some weaknesses around the sample size calculation and expectations of the study. The power calculation is based upon the expectation that a difference of 54 metres will arise between the two groups and this is extremely unlikely since the natural post-rehabilitation fall in 6 minute walk distance is about 54 metres over 5 years (see recent paper from Bart Celli’s group). If the study were powered for equivalence a much larger sample size would be required. Also the 10% loss rate is probably too optimistic. I would anticipate a greater drop-out rate. The authors do not mention whether this is an intention to treat analysis but I imagine that this will only be performed on the survivors though the former may be more interesting.”

Response: The reviewer expresses concern regarding the sample size calculation, which is based on a difference at 12 months between the intervention group and the control group of 54 metres and cites Casanova C et al, 2007 (Bart Celli’s group) as showing about a 54m decline in 6-minute walk distance over 5 years (see recent paper from Bart Celli’s group). If the study were powered for equivalence a much larger sample size would be required. Also the 10% loss rate is probably too optimistic. I would anticipate a greater drop-out rate. The authors do not mention whether this is an intention to treat analysis but I imagine that this will only be performed on the survivors though the former may be more interesting.

We agree that a 10% drop-out rate could be considered as optimistic in this subject group. We had predicted that a 10% drop-out rate may be adequate.
because the subjects would be recruited having successfully completed a pulmonary rehabilitation program, suggesting that they may also be more likely to complete a maintenance study. However, in reviewing the data from Reis et al (2003) a 15% drop-out may be more realistic in our 12 month study. Accordingly, we have altered the sample size and will recruit 38 subjects in each group, which will allow for a 15% drop-out rate. This has been altered in the manuscript p10, line 15. It was an oversight that we did not mention intention-to-treat analysis, which we will perform. This has been included now on p.10, line 7.


We have also simplified Table 1.

I would like to thank you for the opportunity to respond to the reviewer’s comments and for re-considering this manuscript for publication.

Yours sincerely,

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