Author's response to reviews

Title: The effects of a physical activity counseling program after an exacerbation in COPD: a randomized controlled pilot study.

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Author's response to reviews: see over
Dear Editor,

Thank you for having reviewed our article “The effects of a physical activity counseling program after an exacerbation in patients with Chronic Obstructive Pulmonary Disease: a randomized controlled pilot study.” We are grateful for being given the opportunity to revise our manuscript. We have addressed all the reviewers’ comments in a point-by point reply and changed the manuscript according to their suggestions. We sincerely hope that the improved manuscript will now meet the criteria for publication in your journal.

On behalf of all authors,

Thierry Troosters
1. The reviewer questions the pilot aspect of the study and wonders if the study should be considered as a feasibility study. 

*Feasibility studies are used to determine whether an intervention is appropriate for further testing; in other words, they enable researchers to assess whether or not the ideas and findings can be shaped to be relevant and sustainable.*[1] In the present study we might not have gathered enough contextual and feasibility data to support the claim that this would be a feasibility study. Rather, we report on the initial testing of an intervention. When these data would have been more favorable, we intended to carry on the trial until sufficient patients were recruited to be able to come to conclusions. In a feasibility study, the protocol is typically adapted after the preset number of patients is reached.

We executed a power calculation prior to the start of the study. We therefore consider our study to be a pilot study. Information on the sample size calculation was added to the manuscript in the methods section on page 4.

2. The reviewer suggests, when the study is considered a pilot study, that information of sample size calculation should be added.

*This information was added to the manuscript in the methods section on page 4.*

3. Do you have information on the amount of stops and the duration of stops during the 6MWD? Did you perform 2 tests as is recommended by the guidelines?

*In our center, we report the maximal distance walked during 6 minutes. However, we also record amount of stops and duration of stops during the test. Since the reviewer is interested in these data, they are implemented in Table 1 (baseline characteristics) on page 15 and Table 3 (Change in clinical parameters during 1 month) on page 16. The patients that were included in the study were all familiar with the 6MWD, so a significant learning effect was not expected. For this reason and for not burdening the patients too much, only 1 test was performed. The latter sentences was added to the text on page 6.*

4. Elaborate in the methods section a bit more on the telephone counseling. How was the target set, how long did every telephone call last and were barriers to be physically active discussed?
We did not record the duration of the telephone calls. We added to the manuscript that the aim of the study was to strive to the highest level of physical activity as possible during 1 month. Therefore, we discussed with each patient individually which increment in amount of steps they found feasible for the next week. During the telephone calls, barriers to be physically active were also discussed and possible ways to overcome these barriers were provided. (page 5)

5. The reviewer suggests to explain the study of Greening et al. in the discussion in more detail, since it was the first study applying another intervention than standard pulmonary rehabilitation during and immediately after an exacerbation.

This part was discussed in more detail. The following was added on page 8: ‘In a recent study of Greening et al., a first attempt was made to investigate an alternative intervention to conventional pulmonary rehabilitation to improve function and PA during or immediately after an exacerbation. Early rehabilitation, consisting of exercise and resistance training, neuromuscular electrical stimulation and self-management was started within 48 hours after the exacerbation and evolved in an unsupervised home-based program after hospital discharge. The results of this study were comparable with our study and showed a recovery in function and PA. Early rehabilitation and unsupervised home-based training did not result in a better recovery compared to usual care. The study of Greening et al. therefore confirms that home based interventions to improve function or PA during or immediately after hospital admission for an exacerbation might lack efficacy. Individualized pulmonary rehabilitation after an exacerbation may be a better approach in patients after an exacerbation.’

6. Did you correct for important baseline differences in your statistical analyses?

When analyzing the data on physical activity, we corrected for these differences. This information was added to the section on statistics on page 6.

7. Do you have information whether the patients lived alone?

We did not record this information.

8. Can you explain the rather high values of quadriceps strength at baseline?

Quadriceps strength was reduced in the 2 study groups (85±43 %predicted and 71±38 %predicted in the control and intervention group respectively), but these values were indeed higher than previously reported by our group.[2] These findings were
somewhat unexpected, but might be explained by the fact that 2 patients in the control group and 3 patients in the intervention group had a BMI<20 kg/m².[3] The presence of cachexia might lead to an overestimation of the relative value of quadriceps strength. This explanation was added to the text on page 8.

**Reviewer 2**

1. Can you include data on post-discharge pulmonary rehabilitation in the introduction of the manuscript.

   The following information was added to the text on page 3:
   ‘So far, studies concentrated on formal pulmonary rehabilitation to improve physical activity after exacerbations, with contradictory effects. From the 10 studies that have been published on this topic, 4 studies showed an increased level of physical activity after pulmonary rehabilitation.’

2. In the methods section, it is not clear what the primary outcomes is. Insert that the randomization ration of study is 1:1.

   The primary and secondary outcomes of the study are now clearly mentioned in the methods section on page 5. The randomization ratio was also added on page 4.

3. The reviewer suggests to implement information on the sample size calculation. More information should be given whether or not you used an intention to treat analyses.

   The implementation of the sample size calculation was also a question from reviewer 1 and was added to the text on page 4.

   We commented in the section on statistics on page 6 that we included all evaluable patients in the analysis, without excluding patients that were not compliant. In that sense, the analysis could be considered as an –intention to treat- analysis. On the other hand, patients without follow-up data were not included, since it would be difficult to impute missing data in the context of the month post exacerbation.

4. Describe in more detail how the intervention was performed. When were the patients called and what was discussed? What did the patients in the control group receive?

   We subdivided the intervention part in the methods section on page 4,5 in “physical activity measurement and real-time feedback” and “physical activity counseling” to
make it more clear. In the latter part, we discussed that the patients were called on a
time that was most suitable for them. The content of the calls was already included in
the text and consisted of a report of the amount of steps from the previous week,
discussing barriers to be physically active and setting a new goal for the coming week.

5. The reviewer suggests to add legends to the figures and provide information about
safety.

Legends were added. One patient in the intervention group died, no specific data
concerning safety were recorded.

6. The reviewer remarked some typing errors

These errors were corrected.

The reviewer suggested to use “counselling” instead of “counseling”. In pubmed,
“counseling” was used in all articles on this topic. That is why we decided to use this
way of writing. When reporting numbers, we decided to not fully write them, except
when starting a sentence with a number.
References

