Author’s response to reviews

Title: Title App-Based Supplemental Exercise During Inpatient Orthopaedic Rehabilitation Increases Activity Levels: A Pilot Randomised Control Trial

Authors:

Tram Bui (tram.bui@royalrehab.com.au)
Clayton King (clayton.king@royalrehab.com.au)
Ana Llado (ana.llado@royalrehab.com.au)
Darren Lee (darren.lee@royalrehab.com.au)
Grace Leong (grace.leong@royalrehab.com.au)
Anuka Paraparum (anuka.paraparum@royalrehab.com.au)
Ingrid Li (ingridli@live.com.au)
Katharine Scrivener (kate.scrivener@mq.edu.au)

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Response to Reviewer Comments of PAFS-D-18-00197

Reviewer 1

1. It wasn't clear to me whether you knew that the people in the study actually did the supplementary exercise - either with the paper diary for the controls or in the app for the intervention. Could they report that they had done it and then not do it? Then, does it matter whether they actually do it or not?

OUR RESPONSE: The supplementary exercise dose in the control group of this study is participant-reported. You are correct in saying that the participant could have reported they completed the exercise even if they had not done so. We did observe however that with the paper
diary, participants were more likely to not record their supplemental exercise as it was time-consuming – so it may even be under-recorded as opposed to over-recorded.

Within the intervention group, the app automatically counts the number of reps and computes total time. In reality it measures when the app is open and we are assuming that the participant is engaged with the program. The most accurate way of reporting this would have been for covert monitoring. As this was not possible, we chose this simple method of participant self-recorded data and involved volunteers who encouraged accurate documentation. We believe that the data we present is accurate and included it in the results as we believe it provides valuable information on the feasibility of our chosen intervention.

The accuracy of each of these methods has been added to the methods which now reads:

“Data regarding supplemental exercise for the intervention group were reported from the App which recorded information regarding total time, type of exercise, number of repetitions, sets and perceived difficulty as measured by participants. The app automatically counts the number of reps and computes total time when an exercise is selected, thus the data are accurate if the patients are engaged with the program.”

And

“Data regarding supplemental exercise for the control group was collected from their paper diaries, which was collected by the research assistant on discharge from hospital. Participants recorded the exercise they completed in a paper form provided. This form of quantifying exercise dose has been shown to be valid in a rehabilitation setting [Scrivener, K., Sherrington, C., Schurr, K., & Treacy, D. (2011). Many participants in inpatient rehabilitation can quantify their exercise dosage accurately: an observational study. Journal of Physiotherapy, 57(2), 117-122].”
2. At the end of the intervention section you say "the blinded assessor was not a treating clinician or a principal investigator on the study and was a researcher based at Macquarie University". What is the purpose of that blinding? What does that researcher have to do with the study?

OUR RESPONSE: Thank you for pointing this out – we agree that it is unclear. The blinded assessor was involved in completing functional outcome measures at baseline and discharge as mentioned in the ‘Outcome Measures’ section of the manuscript. As it is already mentioned in this section, we have now removed the comment on the blinded assessor in the ‘Intervention’ section.

3. In the Data Analysis section you say "Independent T-Tests were used to compare the means between the two groups". I think you need to be more specific. Did all comparisons use this test? You have reported confidence intervals and p-values. Are all those p-values from t-tests? (t-test should not be capitalised, by the way).

OUR RESPONSE: Independent t-tests were used for all comparisons. We have now included information on the tests used in greater detail. We have also added a comment on the significance level used for the tests. It now reads “The demographic characteristics of all participants were described. A qualitative analysis of the intervention group survey results was undertaken and described. For measures of exercise dosage independent t-tests were used to compare the means between groups. For all measures of physical performance independent t-tests were used to compare the mean change scores between the two groups. Statistical significance for all tests was set at p<0.05.”

4. You have done tests comparing all the characteristics of the people in the groups at baseline. The main CONSORT statement does not support this (although, the version for the pilot and feasibility trials does not mention this specific point). I would recommend taking those tests out.

OUR RESPONSE: The ‘Difference between groups’ column which compares the characteristics of the groups at baseline has now been removed from Table 1 as suggested.
5. In table 2 you have reported confidence intervals for the difference in the totals when the difference in the means would seem more relevant and what you describe reporting in the Data Analysis section.

OUR RESPONSE: As per your comment, the confidence intervals have been removed from Table 2. The mean difference has been kept as suggested.

6. You report results for the subgroup of over 65 years. How many people are in this group? It seems quite bold to report on a subgroup when there are only 20 people in total in the study.

OUR RESPONSE: We agree with your comment. The sections containing data on this subgroup have now been deleted from the manuscript.

7. I would remove Figure 2. I don't think the graph adds anything to the understanding of the paper. You would be better off just talking about it in the text.

OUR RESPONSE: Figure 2 has been removed. The range for amount of supplementary exercise was already included in the text of the original manuscript.

8. In paragraph 1 of the Discussion you discuss the quantitative results - including a very marginal 0.049 p-value. I don't think that these inferences should be made here as it is a pilot study. If these results are credible, then there would be no need for a larger study. I would regard as purely indicative at the piloting stage.

OUR RESPONSE: We agree with your comment and have made changes to the text to reflect this, including removing the marginal p-value. The text now reads: “The results are promising and indicate an increase in the number of repetitions (MD 548.7, 95% CI 95.3-1002.1, p=0.020). However, the results point to the need for a larger, higher-powered study to further examine effects.”
9. Your conclusions should be tied more closely to your research questions, in my opinion. In particular, you have found that the App based supplemental exercise programs are both accessible and feasible in orthopaedic rehabilitation patients.

OUR RESPONSE: We have received our research questions and amended our conclusions accordingly. It now reads – “An App-based exercise program is an acceptable and feasible method of increasing activity levels in orthopaedic rehabilitation patients. As a safe intervention, it also demonstrates the potential to improve functional outcomes. This pilot study should be followed with a larger study with more diverse diagnoses and greater impairments to determine its effectiveness.”

Reviewer 2

1. Background: The first paragraph is somewhat under referenced. Additional references could be added, particularly around the acceptability as a health promotion aid in the community

OUR RESPONSE: We have added a few additional references in the first paragraph in response to your comment.

2. Activity levels: Throughout the paper, there are references to 'activity levels' mentioned - with one of the research questions focussed on increasing activity levels. Potentially influenced by the information in the background (inpatients having low levels of activity, with totals of 8 mins of walking and 398 steps per day), I was expecting the authors to be measuring 'activity levels' of the participants overall. However, it appears that 'activity levels' in terms of outcomes relates only to the additional time spent performing the supplemental exercise program. This needs be clarified throughout the paper. (RQ2 and the heading at line 268 for example)

OUR RESPONSE: We have amended RQ2 – it now reads: “Will an App-Based exercise program increase activity levels of individuals participating in inpatient rehabilitation during their out-of-therapy hours, specifically in relation to the amount of exercise completed?” We have also changed the heading in the results to “Effect of intervention on activity levels in supplemental exercise”.

3. Length of followup: It is noted that the participants were recruited over a 4 week period, but it is not clear how long the follow-up period for each participant was. It appears to be until the completion of inpatient rehabilitation program. If this is the case, please include average time of follow-up (average time as an inpatient) in the results table.

OUR RESPONSE: Yes that is correct. The follow-up period for each participant is the total admission period (length of stay). The average time of follow-up for each of the groups has been added to Table 1.

4. It would be beneficial to include some supplementary material on the tests used to measure the secondary outcomes - this will not be tests known to all readers.

OUR RESPONSE: Descriptions of the physical and functional outcome measures used have been added in the ‘Outcome Measures’ section of the manuscript.

The 6MWT is a self-paced test which assesses distance walked over 6 minutes as a sub-maximal test of aerobic capacity[18]. This test is often performed before and after intervention to assess for a clinically significant improvement and has shown excellent short-term reproducibility[19].

The 10MWT assesses walking speed in metres per second over a distance of 10-metres. It is a safe test that can be easily implemented with minimal facilities and budget[20].

The TUG test is a determinant of falls risk and is used to measure the progress of balance, sit to stand and walking. Originally designed for the elderly population, it is now used in a variety of settings. The test involves the participant standing from a seated position, walking 3-metres, turning around and returning to sitting in the chair. Total test time of 14 seconds or longer has been related to a high risk for falling[21].

The FIM is a universally recognised indicator of severity of disability and is used to assess improvement during a rehabilitation episode. This test is comprised of 18 items (13 motor tasks and 5 cognitive tasks) which are assessed on a 7-point ordinal scale. Total score indicates level of function and can range from 18 (total assistance) to 126 (complete independence). The test is
used to measure functional change during a rehabilitation episode and is generally administered at admission and discharge[22].

5. Paragraphs reporting the results of supplementary exercises (lines 260 and 268) - are these minutes per day, per week, or in total? If it is in total, the average follow-up time per group needs to be noted as well.

OUR RESPONSE: These results refer to the additional exercise performed in total i.e throughout the admission. Average length of stay (follow-up time) for both groups, including SD, has been added to Table 1. In the results, we have also specified that we are referring to the total amount of exercise completed, or the average amount of additional exercise during the admission.

6) Footnote needed for table 1 for *

OUR RESPONSE: Thank you for picking this up. A footnote has now been added in Table 1 – it reads: ‘N = 9 as one participant was unable to perform the test’.