Author’s response to reviews

Title: Exercise Intervention for Unilateral Amputees with Low Back Pain: Study Protocol for a Randomised, Controlled Trial

Authors:

Joseph Wasser (wassejg@ortho.ufl.edu)
Daniel Herman (hermadc@ortho.ufl.edu)
MaryBeth Horodyski (horodmb@ortho.ufl.edu)
Jason Zaremski (zaremjl@ortho.ufl.edu)
Brady Tripp (trippb@hhp.ufl.edu)
Phillip Page (ppage@performancehealth.com)
Kevin Vincent (vincekr@ortho.ufl.edu)
Heather Vincent (vincehk@ortho.ufl.edu)

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I want to thank the reviewers for their time and comments. All comments were very fair and allowed for improvement to the study protocol/manuscript.

Reviewer #1:

1. Line 29 - Consider randomised controlled trial as a keyword.

Author Reply: Thank you for your suggestion. We have included it as a keyword.

2. Line 95 - You plan to recruit from a major regional prosthetics center and from the community. I would like a bit more information on how to plan to recruit from the community in particular.

Author Reply: Additional information has been included (examples: via relationships with local prosthetic clinics and amputee support groups, flyers, online ads and social media posts).
3. Line 118 - Add 'be' after 'will' and before 'made'.
Author Reply: Correction has been made.

4. Line 137 - Replace 'off of' with 'on'.
Author Reply: Correction has been made.

5. Line 144 - Is it therefore a requirement of study inclusion that participants have access to Skype or Facetime? What happens to participants that don't have access? How then is exercise supervised?
Author Reply: Thank you for this catch, one of our inclusion criteria is access to online resources for face timing – we have included it here in this revision. It is a requirement for participants to have access to video chat for weekly updates and exercise monitoring.

6. Line 159 - Participants in the control group are asked to refrain from starting any new strengthening exercises and phoned monthly to determine if there are changes in their lower back pain symptoms. I would like to know if you are (or have considered) requesting control participants to report if they did start new strengthening exercises during the control period.
Author Reply: During the monthly check-in with waitlisted control subjects, we will make note of any changes to exercise, pain, or medication. This is now clarified for the reader.

7. Line 166 - Please can you make clearer when all outcome measures will be collected. I think it would also be useful to add this to Table 2.
Author Reply: Clarifications have been made in-text and on figure 1/table 2.

8. Line 171 - Above this line you may want to consider a subheading 'Primary Outcome Measures' as you have a subheading for secondary outcome measures.
Author Reply: This heading is already in place.

9. Line 179 - Info on medications will be captured but it is not reported how this will be done.
Author Reply: During initial surveys, questions regarding scheduled medication(name, dosage, frequency of use) will be collected, as well as known PNR medications that the participant takes. During weekly updates, questions will be asked if any changes to scheduled medication have
occurred as well as what PNR medications (name, dosage, frequency) have been taken for the week. All of these measures will be self-reported.

10. Line 193 - Presumably participants will need to attend a clinic to capture secondary outcome measure data - this is not made clear. You might also want to remind readers in this section that assessors will be blinded.

Author Reply: All baseline and post-test outcome measures will be collected at our biomechanics laboratory. Sentence reads All of the following secondary outcome measures will be collected the UF Human Dynamics Laboratory in the Orthopaedics and Sports Medicine Institute (lines 198-199)

11. Line 247 - You state that StepWatches will be worn for a week - have you considered fidelity to this?

Author Reply: Participants will be contacted at the end of every day during the 1 week period to collect steps. Though we cannot guarantee all participants will use their pedometers, we have improved our ability to obtain good data by contacting the participants for the visual image of their Stepwatch readings for each day of that week.

12. Line 261 - As per the SPIRIT checklist, have you considered plans to promote quality in data entry and DMC involvement?

Author Reply: With respect to a Data Monitoring Committee (DMC), we have an internal Departmental Auditing procedure that consists of a team of clinical coordinators and the Director of Research – but we do not have a paid DMC. This team reviews ongoing trials on a quarterly to biennial basis depending on the size of the study. They review the data online in the REDCap system, the study logs and paper datafiles of measurements takes to ensure the rigor that is expected of clinical trials. We also perform spot random audits of files twice a year to ensure that the quality is maintained over time.

13. Line 248 - Change 'as' to 'a'.

Author Reply: Correction has been made.

14. Line 295 - Drop 'be' after 'will'.

Author Reply: Correction has been made.
Reviewer #2:

Abstract: first sentence "Atraumatic lower limb amputation is a life-changing event for approximately 185,000 persons each year". Can you please state if you mean 185,000 worldwide/in the US/in North America... ? and based on the age range (18-60) that you are using, does this mean 185,000 adults, or include under 18s or over 65s too? ... just for clarity.

Author Reply: This figure was collected for the United States by the national organization, the Amputee Coalition. This has been clarified. Moreover, the data that was used to report did not clarify age range, so assumptions are made as individuals.

Intervention description: you have mentioned progression using bands with greater resistance, but do you have a plan if they are unable to perform with the lowest resistance band - ie will you allow them to continue but start at a lower level such as performing the movement with no resistance band?

Author Reply: Modification of exercises to accommodate such things as pain are available. As for the resistance of the bands, the lowest resistance is 3.7lbs which is low enough for every participant to be able to perform with. The study population is not a frail one, they are typically younger and relatively strong.

Stats: the study flow diagram seems to suggest you will only include in the analysis those who complete the programme (ie study flow suggests n=32), can you just clarify if this is the case, or whether you would use intention-to-treat (ITT) to include those who have dropped out or been excluded along the way for whatever reason. If using ITT what will you use for the "missing data" - LOCF/BOCF/WOCF.

Author Reply: Thank you for this fair question, in retrospect this was not clear. Our goal was not to perform the ITT as this was a relatively small study and we surmise that if we included those with partial data and low participation rates that any treatment effect would wash out. For those who are not compliant, their data will not be included in the final analysis (added line to 166-167). Our hope is that with a subsequent larger study, we can perform ITT and include all participants.