Reviewer's report

Title: Exoskeleton-assisted Gait Training to Improve Gait in Individuals with Spinal Cord Injury: A Pilot Randomized Study

Version: 0 Date: 12 Jul 2017

Reviewer: Mohamed Sakel

Reviewer's report:

Reviewer's comments:

"Exoskeleton-assisted Gait Training to Improve Gait in Individuals with Spinal Cord Injury: A Pilot Randomized Study" is a welcome study in the emerging new technology based rehabilitation for spinal injury

The report of this Pilot study is consistent with the Standards of CONSORT Extension 2010 Statement regarding Pilot & Feasibility studies, Table 2

However, the authors did not mention the rationale of the number of patients included in this study. I accept it's not possible to demonstrate any statistical calculation of the sample size.

Scientific background and explanation of rationale for future definitive trial was well established by the authors. However, they could have articulated the reasons for a randomised pilot trial preceding a definitive RCT.

The entire cohort of patients was incomplete spinal injury. They could have explained the reason for excluding complete spinal injury since other exoskeleton trials in spinal injury included people with complete spinal injury. Reference: "Results of the first interim analysis of the RAPPER II trial in patients with spinal cord injury: ambulation and functional exercise programs in the REX powered walking aid". Journal of NeuroEngineering and Rehabilitation (2017) DOI 10.1186/s12984-017-0274-6
http://jneuroengrehab.biomedcentral.com/articles/10.1186/s12984-017-0274-6

Outcome Measures: The authors have used appropriate measures. However, there is an inaccuracy in reference 23 for Timed Up & Go test (TUG). Reference 23 is the study by Rossier P (2001) where they compared 4 outcome measures of mobility which did not include TUG. This needs to be corrected. Also, TUG is described as an indicator of risk of falls which is not accurate. TUG represents functional mobility and the authors' choice of TUG is correct but not
for the reason expressed by them. The risk of falls can be assessed by Berg Balance Score (BBS) or Modified Falls Efficacy Score. BBS has cut off values which reflect hierarchy risk of falls.

Statistical analysis: Due to modest sample size of 9, no inter-group comparisons were attempted. However, it would be interesting to see any differences even if statistically insignificant. The stated hypothesis was exoskeleton group (EGT) will perform better than the Conventional group CPT.

The authors correctly identified the weakness of the study for having dissimilar baseline characteristics of the two randomised groups. The CPT group has better baseline functions as measured by the outcome scales used in this study. For example, the EGT group's endurance average score 50 m vis a vis CPT group's average 6 MWT of 147 m. No wonder, the CPT group couldn't improve much, relative to EGT group. Hence, statistical significance of the difference need to be considered with less enthusiasm. This could explain in Table 1 and Table 2 of the result section. By the way, There is another Table 1 describing "Participant Characteristics " - page 8. To avoid confusion, there needs to be accurate numbering of the Tables. The problem of this biased grouping despite randomisation weakened the study. The authors described the randomisation procedure as through" drawing lots". Perhaps, in the definitive trial , a different randomisation procedure will be employed. The major flaw / bad luck is reflected in fig 1, the CONSORT Diagram. From 44 eligible patients, only 9 patients met inclusion criteria. This practical challenge has to be addressed before the future definitive RCT is planned. This may reflect the design characteristics of the device that they used. Unless, this issue is resolved, generalizability of future RCT or translation into clinical practice will be difficult regardless of the statistical findings. Perhaps, multi-centre will be needed to address this problem. This screen failure issue needs some reflections by the authors.

Comments on written English language: Well written. However, on page 3 para 2, line 3, "deliberate observance of task" is difficult to understand. Do the authors mean performance of task? In the discussion chapter, page 11, the sentence starting with " Our experience----------" is a compound sentence which needs to be simplified into 3-4 sentences please.

Overall comments: The authors have conducted an important study on an important topic which is publishable with minor amendments made from above comments.
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