Reviewer’s report

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

Version: 0 Date: 16 Jul 2017

Reviewer: Janice Eng

Reviewer's report:

This paper reports on findings from 7 participants with incomplete spinal cord injury who completed 3 weeks of either exoskeleton or conventional physical therapy to improve gait. The findings may inform the design of future larger clinical trials. However, the presentation and the discussion of the findings should be re-written to focus on the usefulness of this study's findings for future research. Overall this paper needs to be edited for readability and grammatical errors, of which there are many throughout.

Background:

The background should discuss chronic SCI specifically, given that the participants recruited were 2-34 years post-injury. Exoskeleton gait training may benefit acute iSCI differently than in chronic iSCI (more atrophy, deconditioning perhaps in chronic iSCI).

In the background, the authors state that "effectiveness of exoskeleton-assisted gait training for individuals with SCI remains unclear"; however, the purpose of this pilot study or its results do not relate to "effectiveness", which is determined through a Phase III clinical trial. This should be reworded to efficacy.

The within-group differences are analysed and reported, however no between-group comparisons were made; therefore the authors should not be hypothesizing greater improvements in the EGT group COMPARED to the CPT group.

Methods:

The number of subjects screened, enrolled, and completed the study should not be reported in the methods, and should be included in the results section instead.

Please elaborate on the randomization process of drawing lots, was this done manually or via a software? Was it a 50/50 allocation ratio?
The EGT group received 60 minutes of therapy and 30 minutes of set-up, while the CPT group received up to 60 minutes; please clarify if all CPT participants received a full 60 minutes for each session and perhaps comment on the extra time spent with researchers in the EGT group.

Validity of measures chosen for iSCI should be provided.

Why was balance not measured?

The statistical analysis should be determined a priori, and so the comment that between group differences were not analysed because of small sample size should be removed or reworded.

Results:

Do not need to include the exercises the CPT group underwent (should be in methods instead).

"As expected, subjects in EGT group spent significant more time on walking … compared to subjects in CPT Group" - this should be reworded to substantially, as no between group comparisons were made and so significance is misleading.

At times, stride length and step length are used interchangeably but conceptually are different. Please re-word appropriately throughout the gait characteristics. There are also mistakes in reporting results, e.g. reporting on the right side but then commenting on left side.

Discussion:

There is too much focus on potential mechanisms (not measured in this study) for the observation of non-significant, minor, or sparse improvements in the EGT group; there were improvements noted in the CPT group as well, and so excessive focusing on the mechanisms for improvement does not seem appropriate given the lack of findings of superiority. Instead, please comment on how findings might inform future larger scale studies, how it might determine sample size, inclusion/exclusion criteria, intervention duration, etc.

Paraplegic vs quadriplegic - please comment on how the exoskeleton training may be different or have different effects based on impairment.
The participants in the CPT group scored much better than the EGT group at baseline on various measures; please comment on how this affects findings or may bias findings. It is more difficult to make changes in stride length, strength, or functional tasks if they are already closer to normal (less room for improvement).

Though mentioned briefly in the limitations, greater discussion regarding impairment/injury/functional level and how they might have impacted results should be provided.

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