Author’s response to reviews

Title: Cardiovascular rehabilitation early after stroke using feedback-controlled robotics-assisted treadmill exercise: study protocol of a randomised controlled pilot trial

Authors:

Oliver Stoller (oliver.stoller@bfh.ch)
Eling D de Bruin (debruin@move.biol.ethz.ch)
Corina Schuster (c.schuster@reha-rhf.ch)
Matthias Schindelholz (matthias.schindelholz@bfh.ch)
Rob A de Bie (ra.debie@epid.unimaas.nl)
Kenneth J Hunt (kenneth.hunt@bfh.ch)

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Author’s response to reviews: see over
Dear Sir or Madam

We greatly appreciate the review of our manuscript. Below we have listed the reviewer’s comments and recommendations, whereas we give our response to every point brought forward.

All changes within the manuscript are marked in blue.

We hope that this revision of the manuscript is now acceptable for publication in BMC Trials.

Yours sincerely

Eling de Bruin, PhD

Reviewer’s comments to the author:

1. Because this is a pilot study, it would be helpful to have a little more information as to how it fits in the overall research plans. What kinds of findings, for example, would lead the researchers to undertake (or not undertake) a full-scale trial?

   Our answer: We added further information in a novel “Conclusion” section: “Our overall research plan aims to further develop and implement robotics-assisted devices for cardiovascular rehabilitation early after stroke. The approach presented here has been tested previously in a phase II clinical trial that has shown feasibility of the concept for assessment of aerobic capacity and guidance of cardiovascular exercise in severely impaired individuals. The phase III clinical trial described here aims to determine early indications of the presence and magnitude of efficacy as well as to refine the definition of the experimental protocol. If this trial is able to show reasonable clinical feasibility and to demonstrate having potential for efficacy on the primary outcomes (aerobic capacity), further full-scale trials would be warranted to investigate overall effectiveness of this approach. In case of poor feasibility and low efficacy, the concept might have to undergo further revision and development to optimally support cardiovascular exercise in severely impaired populations.”

2. The expected time of completion of enrollment should be included in the Trial Status section.

   Our answer: We completed the Trial Status section to: “The trial was designed and commenced in 2012. The expected time of completion of enrolment is June 2014.”