Author's response to reviews

Title: How to improve walking, balance and social participation following stroke: a comparison of the long term effects of two walking aids - canes and an orthosis TheraTogs - on the recovery of gait following acute stroke. A study protocol for a multi-centre, single blind, randomised control trial.

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How to improve walking, balance and social participation following stroke: a comparison of the long term effects of two walking aids - canes and an orthosis TheraTogs - on the recovery of gait following acute stroke. A study protocol for a multi-centre, single blind, randomised control trial.

Clare Maguire, Judith M Sieben, Florian Erzer, Beat Goepfert, Matthias Frank, Georg Ferber, Melissa Jehn, Arno Schmidt-Trucksaess and Rob A de Bie

Dear Sir or Madam,

I would like to thank the reviewer of the study protocol mentioned above for his careful review and considered comments. I would like to take this opportunity to answer the questions raised in the review.

1) The first question was „I wonder why you restricted the inclusion to patients who were initially hemiplegic and recovered to un-aided walking? What is the rational?“

The inclusion criteria in question are stated in the protocol as follows „All subjects (1) will be patients with hemiplegia following a first unilateral stroke, (2) will score at least level 3 on the Functional Ambulation Category (FAC) [39] (able to walk unaided on even ground but requiring verbal prompts and stand-by help without body contact)“

We decided that it is important to include only patients suffering from a „first time
stroke" so that we are able to exclude any possible signs and symptoms from previous strokes which could influence walking recovery or the response to the given walking aid. In this way we have tried to exclude possible confounding factors.

The patients must also have reached Function Ambulation Category 3 (able to walk unaided on even ground but requiring verbal prompts and stand – by help without body contact) – so that they are able to use the interventions. If the patients did not have some degree of walking independence they would not be able to use canes or TheraTogs. We have defined the walking ability as the minimum necessary to be able to participate in the study.

This ability level also represents the clinical situation regarding giving stroke patients walking aids. At the ability level described by FAC 3, therapists would consider which walking aid would be appropriate for a patient to support independent walking. This is the point at which patients would be encouraged to walk with supervision and/or minimal assistance within the rehabilitation department. We therefore consider that this inclusion criteria is necessary for practical reasons and that it contributes to the clinical relevance and generalizability of the study.

A sentence was added to the text of the inclusion criteria paragraph in the manuscript to clarify this point (page 9, highlighted green).

2) The second question asks “Why is the time from symptom onset not considered as an inclusion criterion since it might influence cortical plasticity?”

We agree that this is an important consideration and that time since stroke may be an influencing factor on cortical plasticity and on the response and recovery due to the interventions. However we considered that:

1. As the study subjects are all recruited from post-acute rehabilitation departments the recruitment environment will ensure that the majority of patients will have suffered stroke within the last few months.

2. We wanted to reflect the clinical reality of providing walking aids in order to optimise the clinical relevance of the study. The provision of walking aids in practice is determined primarily by the walking ability of the patient.

3. Time since stroke will be documented for all patients and a covariate analysis will be completed. In this way any response difference due to varying times since stroke will be recognised.

3) The third question asks: “Why does the site of stroke not play a role in recruitment?”

Physiotherapy treatment for stroke is currently based on the presenting signs and symptoms of patients rather than the physiological differences. The prescription of walking aids is decided in relation to a patients walking ability and the support considered necessary to facilitate independence. The site of stroke is not currently considered in this clinical decision.

It is also not clear at this point what influence the site of stroke may have on the
patients response to rehabilitation treatment. It would therefore not be possible to define logical in- or exclusion criteria relating to site of recovery as the prognostic influence in not known. The site of stroke for each patient will however be documented and post-hoc analyses will be made to assess whether site of stroke plays a role in response to the gait aids. This method may allow prognostic conclusions related to site of stroke, walking recovery and response to walking aids to be drawn.

Thank you for taking the time to read this reply. I hope that the rational behind the decisions described above is clear.

Best wishes,
Clare Maguire.