Reviewer's report

Title: Comparison of embedded and added motor imagery training in patients after stroke: study protocol of a randomised controlled trial using a mixed methods approach

Version: 3 Date: 28 May 2009

Reviewer: David M Kent

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This protocol aims to test embedded versus added motor imagery training after stroke.

Before this protocol can be accepted for publication, there are a number of issues which need to be clarified.

1. Please clarify the primary outcome. It appears that the primary outcome is the time it takes to perform the task. This is measured at several different time points including immediately after therapy and at follow-up. At which time point is the primary outcome ascertained? If other time points will be used as outcome measures, or if changes in time to perform the task will be used, these should be specified as secondary outcome measures. An overall count of the number of different secondary outcome measures would also be helpful, since many different scales and many different time points are measured, and each measurement might be performed in different ways (e.g. simple averages over individual, or pre-post differences, etc.)

2. What are the inclusion and exclusion criteria for enrollees, including age, time since stroke, comorbidities, etc.

3. Regarding the power calculation, the trial appears to be underpowered. The effect size chosen was based on the effect size of MI versus control. Presumably the effect size of two different MI interventions will be much smaller. Although not previously compared in the stroke setting, an indirect estimate may be available if both types of MI were compared to a similar control, or if the two interventions were compared in another setting. In addition, the one-tail hypothesis testing does not seem appropriate for this study.

4. The two interventions (added or embedded MI) seem non-comparable in several respects. In particular, with embedded MI, the physiotherapist spends 45 minutes with the patient, while with added MI the physiotherapist is in direct contact with the patient for only 30 minutes per session. This needs to be better defended or addressed as a limitation of the study.

5. Please described the process of randomization/concealment.

6. Pls. specify whether the primary analysis will be based on completers only, or
if outcome measures of non-completers will be obtained and included in the primary analysis.

7. It was unclear what the purpose of the qualitative study was and how it might relate to the results of the randomized trial.

minor point: on page 11, it states that randomization is used to ensure "external validity". Randomization (of a sufficiently large sample) ensures internal validity (i.e. non-biased comparison). External validity depends on the target of inference.