Reviewer’s report

Title: Enhancing activities of daily living of chronic stroke patients in primary health care by modified Constraint Induced Movement Therapy (HOMECIMT): study protocol for a cluster randomised-controlled trial

Version: 1 Date: 23 May 2013

Reviewer: Peter Sandercock

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Home CIMT

Major Compulsory Revisions

1. In the section ‘Novel aspects of HOMECIMT it states: ‘CIMT is a therapy shown to be effective in the treatment of stroke patients largely independent of 3 time post stroke’ and three references are cited [8, 9, 10]. However, the 2009 Cochrane review of the topic identified We 19 studies involving 619 participants and was able to include data from Six trials (184 patients). They concluded ‘CIMT …. is associated with a moderate reduction in disability assessed at the end of the treatment period. However, for disability measured some months after the end of treatment, there was no evidence of persisting benefit. Further randomised trials, with larger sample sizes and longer follow up, are justified.’ The background section should include a reference to this paper, and the authors should search the literature for published reports of CIMT that have appeared since that review, to provide a more comprehensive background to the HOMECIMT study. To my knowledge, the field is moving rapidly.

2. The Cochrane review ends with some comments on the ‘implications for research of the completed trials’, and the authors should mention how their trial addresses these points:

It is likely that additional trials investigating CIMT as a rehabilitation technique would be worthwhile if they: consider disability or arm motor function as the primary outcomes; include a validated quality of life measure as one of the outcomes; recruit a larger sample (minimum of 74 participants for arm motor function measures); involve a control group under active treatment, since CIMT involves a certain amount of exercise; explore benefits for longer follow-up periods (one year); and include all randomised patients in their analyses.

3. In the sample size calculation, the source of the parameter estimates (e.g. intraclass correlation coefficient is given, but it is not clear that the source data will be appropriate for the population to be studied (i.e. are the patient characteristics in the cited studies similar to the planned study population comparable). Some more detail on the justification for the sample size estimates would be helpful.

4. The data analysis section sets out the overall plan. Please state if a more
detailed analysis plan be prepared and finalised before the code is broken and the main analyses performed?

5. The acceptance of 15% loss to follow-up is very surprising. The CONSORT statement expects all randomised subjects to be accounted for at the end of the trial. The authors should clarify what they mean by ‘loss to follow-up’. At the very least, the vital status (dead/alive) at 6 months should be known for all participants. The strategies to maintain retention of the subjects on follow-up and methods to trace those not attending follow-up should be stated.

6. Recruitment. It would be helpful to have some indication of the source of referrals to the study, and how patients were invited to join. If a patient is unable to write because of their stroke, how will consent be obtained?

7. How will the recruitment of patients to the study be securely recorded? In a trial where individual patients are randomised via a central office or computer system, the system records the moment the patient is recruited, and retains sufficient identifiers that the patient can then be traced even if the participating clinician does not return data forms. It would be helpful to have more details of the process of recording the recruitment of individual patients.

8. Some details on the trial oversight arrangements should be included: is there a trial steering committee?, is there a data and safety monitoring committee (I presume not, but that should be stated)?

9. Reporting of results. The CONSORT statement would expect the results to be presented in the context of a systematic review of the existing RCT evidence; a mention of whether this is planned in the protocol would be of interest.

Discretionary revisions. In places, the English is rather awkward, e.g. 'An explicit participation-oriented therapy concept is lacking' and other places it is rather technical and difficult for the non-expert reader. If possible, a review of the writing by a native English speaker would be helpful.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

'I declare that I have no competing interests'