Reviewer's report

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

Version: 1 Date: 15 July 2013

Reviewer: Sandra Eldridge

Reviewer's report:

General comments

This is overall a reasonably good protocol, detailing much of the relevant information that would be required to be reported in a main trial by the CONSORT extension for cluster randomised trials. Participants are being recruited prior to randomisation which avoids one of the major sources of bias in cluster randomised trials.

Major compulsory revisions

1. I found the explanation of the underlying rationale for this trial confusing, however, and the discussion of the choice of outcomes. The discussion about the primary outcome seemed to suggest that participation was a desired outcome, but the background and the abstract seem to be suggesting that participation is a therapeutic approach. I think the background, the background section in the abstract, and the primary outcome section need rewriting to make it clear how participation is being viewed, and certainly the sentence that begins "Participation, defined as...." should be rewritten as this definition is confusing and the sentence was very unclear to me.

2. In the sample size calculation I don't think the last sentence which says the study aims to include 180 patients and 130 practices is correct - surely it is 60 practices? Also I could not replicate the sample size calculation exactly and think the authors should check this. If I have understood correctly, a standardised effect size of 0.5 requires 63 in each group without adjusting for clustering and the design effect with a cluster size of 3 and ICC 0.05 is 1.1. This does not result in 75 individuals being required in each group?

3. I am surprised that in the sample size calculation drop out was only allowed for at cluster level. This should be explained.

4. The inclusion criteria are clear but it would be helpful to specify who makes the judgement about inclusion - I am presuming it is the therapist? Is there any danger that later in the process the research team judge a patient ineligible? There should be some explanation about this, particularly as patients are recruited before randomisation but presumably do not have the intervention until after. Circumstances may change.
5. The authors should explain how attempts are made to keep assessors blinded since it would be possible to become unblinded during home visits.

6. I think the decision about the co-primary outcomes should be reconsidered, especially given the stated strategy of analysing them in sequence. This is unusual and does not seem justified. I would suggest it would be much easier to use a single primary outcome.

7. While there may be none anticipated, the authors should discuss potential unintended harms.

8. Is this an efficacy or an effectiveness trial? The authors state they want to evaluate efficacy but without a tightly controlled control group intervention I am not sure how this is possible?

Minor essential revisions

9. The study should be described as a 'parallel' cluster randomised trial, rather than 'prospective'.

10. remove the words "(at least one patient)" from line 12, page 9. These seem superfluous and do not help the reader.

Discretionary Revisions

11. page 8 - recruitment section - More detail could be added about how the areas in Northern Germany were selected; this is not clear.

12. At the bottom of page 15, I did not understand the phrase "randomisation is performed regionally" since this seems slightly at odds with the earlier description of randomisation.

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, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests