Reviewer's report

Title: Development of a complex oral health care intervention after stroke: using a mixed methods pilot study to inform the design of a randomised controlled trial.

Version: 2 Date: 16 March 2011

Reviewer: Allan Donner

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I will restrict my comments to those of a statistical nature.

Page 6:
The authors state that “Stroke is a multifactorial disease, with some clinical heterogeneity across individual patients. In the past “cluster randomization has been used to ensure such heterogeneity does not contribute to outcome heterogeneity and in turn add a further dimension of complexity to any proposed study”.

This statement requires further elaboration (as well as a reference to the study referred to.). That is, it is not clear how “cluster randomization ensures that clinical heterogeneity does not contribute to outcome heterogeneity “.

Page 8:
More detailed description of the nature of the site (eg, locale, type of patients seen, level of care provided) would be useful.

Page 11:
There is considerable attrition of patient numbers from baseline to Time 2 in table 3 (23 patients at baseline with only only 9 patients at Time 2) . Similarly in Table 4, there are 32 patients at baseline with only 8 patients at Time 2 . Some detailed discussion of the reasons for such heavy attrition and the implications for interpretation of the trial results should be given. The fact that Time 2 in Table 3 is really an average of responses taken at several different time points also complicates the interpretation, with similar interpretational problems involved in the table 4 results.

Page 13:
It is misleading to only report the statistically significant results in Table 2. All results should be reported, whether significant or not (perhaps in a separate file). Also it would be helpful if it were made clear that only the T-F and F-T answers enter into the statistical analysis involving McNemar’s test.