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: 17 January 2011

Reviewer: Ian Needleman

Reviewer's report:

This is an interesting report of the development of an oral care intervention for patients who have experienced a stroke. The oral health care of hospitalised patients is problematic and the literature is not blessed with studies that have attempted to employ rigorous research methodology. Furthermore, designing and conducting such studies is challenging. The authors of the present study make a welcome contribution to the literature and further revision will help to bring out the best of this study.

Major compulsory revisions:

1. Introduction is interesting but much too long. I recommend focusing on a concise background/rationale to the study. The existing introduction is more of a treatise on oral health care and complex interventions.
2. Methods: Could you please describe in some detail the content of the individual care plans?
3. Methods: Nursing staff training. This is clearly important. Can you please describe how this was designed and validated?
4. Methods: Can you please describe how the individualised OHC was designed/developed by staff?
5. Methods: Outcome assessment. Can you please describe the training and levels of agreement/accuracy for outcome assessment i.e. dental/denture plaque.
6. Methods: How was a diagnosis of chest infection made/validated?
7. Methods: Oral health related quality of life. Could you please explain/justify why two methods were employed i.e. GOHAI and OHIP.
   a. The plaque measures are unlikely to be normally distributed. Was this tested? Non-parametric methods are probably more appropriate.
   b. I can’t see the value/appropriateness of using the best and worst scores.
9. Discussion. Some aspects of the intervention were well not received... including foam swabs. In view of the recommendation/evidence against using foam swabs e.g. British Society of Disability and Oral Health, can you explain why these were included in the intervention? The use of foam swabs should be discouraged for oral health care.
Minor essential revisions.

1. Methods: Service level intervention. The second sentence ‘We defined.... is long and its meaning is unclear.

2. Results: Patient level – dental plaque. There appears to be a contradiction between the statement that patient consent was not required before staff could assess or care for the patient’s oral health and the following statement that consent related to permission for the research team to accesses to the individuals patient’s healthcare.

3. Results: The results section contains details of methods. These should be moved to the methods section.

4. Results: Dental plaque data. Six quadrants – I guess you mean six ‘sextants’. This appears elsewhere.

5. Results: Dental plaque data. ‘As teeth are only as clean as the dirtiest tooth.... It isn’t dirt but dental plaque. Please reword.

6. Discussion: It would be helpful to summarise concisely what was learnt from the pilot for the full study.

7. Discussion: Summary of main findings. ‘The main outcome of this study was the successful development.... How success determined?

8. Discussion. Implications for future research. Why is the trial unlikely to involve a mixed methods approach? The pilot seems to have highlighted the value of such an approach.

Discretionary revisions.

9. Table 4. Q1 seems to be missing.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I am engaged in similar research but do not feel that I have any conflict of interest