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.

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Reviewer: Martin s Dennis

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This paper addresses a clinically important topic. The authors describe their attempts to design and implement an intervention which aims to improve the services, staff training and care of patients relevant to Oral Health in stroke patients. They have applied both quantitative and qualitative methods to describe these.

I did not find the paper very easy to understand. There are quite a few sentences which don’t seem to make sense. Some concepts (system levels, dimensions) which they use are not clearly described or defined. The ease of reading is not helped by having so much in supplementary files.

Major Compulsory Revisions - None
Minor compulsory revisions

Abstract

1. “Our OHC intervention was informed by multi-disciplinary expert review of the evidence on OHC following stroke and patient and health-care worker views on content and feasibility.” I presume they mean that the development of their intervention was informed ....

2. “At each level the intervention was designed to cascade in succession on subsequent dimensions of care, ultimately contributing to patients’ OHC.” It is unclear what they mean by level as distinct from dimensions?

3. “Our pilot data will inform the design and implementation of our planned progression to a larger randomised intervention study” The reference to “larger” suggests that they have already done a small RCT. It is not clear that they have.

Introduction

4. This is well written and largely clear when talking about previous work on area of OHC. However, they move on to say “Others describe complexity at a systems level (14). The extent to which the intervention has to be adapted or modified on an individual or local systems level is also a factor (6)” It is unclear what they mean by “system levels” Later they refer to patients levels and service levels which further confuses the reader. What is the difference between a dimension and level?
5. In the statement “In the past cluster randomisation 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.” It is unclear whether they are emphasizing the randomization or the cluster.

Methods

6. It is unclear how long before and after the training the staff were assessed with respect to their knowledge and attitudes?

7. “As indicative of one dimension of complexity within this OHC intervention, staff were not only participants in receipt of elements of the intervention, but they were also responsible for the delivery of the intervention at patient level.” I am not sure this makes sense – it could be better phrased.

8. “Other aspects of the intervention at this level included…….” Unclear what this level refers to.

9. “Patients’ OHC was provided by staff that had received specialist OHC training, access to the equipment, products, assessments and protocols of care (detailed above) and were thus better supported in their provision of OHC.” This sentence does not make sense and they were better supported than who?

10. The incidence of chest infection (23) was also monitored throughout their involvement in the study. Does this just mean while they were in the stroke ward?

Results

11. Not sure what AG is?

12. There is considerable duplication between the text and Table 1

13. When the authors describe their quality of oral health measure they refer to change but it is unclear whether the baseline is before their stroke and admission or simply on entry to the study.

Discussion

14. The authors state that “The main outcome of this study was the successful development and implementation of a complex OHC intervention.”. However, although they clearly developed an intervention I am unclear what their criteria for success in implementation were? Were these set out before implementation?

15. Where possible for data collection purposes we would seek to avail of the support of the UK Stroke Research Network. This seems odd use of the word avail?

16. The following sentence does not make sense “Such a multi-dimensional,
pragmatic approach to the development of the intervention and trial will address ensure the planned trial will address some of the methodological weaknesses of previously conducted work in this topic area."

Tables

17. 4 and 5 Quite difficult to understand – not sure how to make sense of data collected over very varied times. A pity did not follow up patients after discharge. However where there are changes over time it seems to suggest that patients have more problems after baseline – does this reflect worsening oral health or increase concerns about this. How does this worsening support the notion that the implementation of the OHC was a success?

18. 6 – so all the patients had a length of stay of less than 3 days??I presume H = hospital and Hm = Home but not stated. Discharge from pilot site before or after what? The interview??

Discretionary revisions

1. It is surprising that the researchers did not attempt to assess the amount and quality of OHC given to patients before staff had been trained. Surely this would have been informative.

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:

In have wroked closely with some of the authors on other projects. I am also on the committee which granted this group the funding for this study.