Author's response to reviews

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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Author's response to reviews: see over
Dear Trials,

Please find attached a revised version of manuscript 162551794499263 originally entitled *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*. In light of the comments from the reviewers this has been adjusted slightly to - *Developing and evaluating the implementation of a complex intervention: using mixed methods to inform the design of an oral healthcare after stroke randomised controlled trial.*

We have taken on board the reviewers comments and adjusted our manuscript in response. These comments and the resulting changes have been detailed below. Adjustments to the text have been marked within the submitted document (where there was some restructuring and large sections of text were simply moved to a different location within the manuscript, only the text in its new position has been highlighted for ease of review).

In light of the comments provided by the expert reviewers the manuscript now has a new emphasis on the background to the methodology, design and evaluation components. As a result of these changes we would like to suggest that the manuscript might perhaps be more appropriately considered as a methodology paper within Trials, but this is merely a suggestion.

We can confirm that the authors have no competing interests. We look forward to your response to this revised manuscript.

Sincerely,

Marian Brady  
Reader, Director – Stroke Research

On behalf of the project team:  
Dr. Marian Brady  
Prof. David Stott  
Prof. John Norrie  
Mr Campbell Chalmers  
Ms Bridget St George  
Dr. Petrina Sweeney  
Prof. Peter Langhorne
Reviewer's 1 report
Main comments from Reviewer followed by response/action:

1. 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.

We have attempted to address these issues in a number of ways – providing more methodological detail and rational for the approach taken within the background, restructuring the methods and results sections, and additional adjustments in response to some specific comments from the other reviewers (particularly Reviewer 4 as detailed below) have further improved the understanding of some of the concepts described.

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 ….

Adjusted to read
“….Working with an expert Advisory Group (AG) comprised of patient and carer representatives, specialist stroke nurses, physicians, speech and language therapists, dieticians, occupational therapists and dentists from across Scotland the research team had reviewed nationally and internationally published OHC assessment and protocol tools for suitability of use within our planned complex intervention (20). The AG concluded the available tools were inadequate and so, through an iterative process, we drafted and refined a stroke-specific OHC assessment and protocol. The assessment tool aimed to comprehensively address all aspects of OHC while the protocol aimed to guide the development of an individual plan of care (for example in terms of the frequency of care or use of products for specific oral health conditions) which would also facilitate patients’ return to independent OHC.”

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?

Adjusted and expanded upon within the text. Now consistently use the terms level or system with the following explanation of system provided within the background...

“…Others describe complexity at a systems level (14) urging careful consideration of the clinical context in which an intervention is delivered. In practice, both the intervention and the systems within which it operates are relevant thus the number of systems could also be considered in relation to the degree of complexity. For example, an OHC intervention is delivered to a patient, by staff operating as a team within a ward, which in turn is nested within a hospital which may be further supported by external specialist dental support services (as required). For the OHC intervention to work the intervention must function within and be supported by the team, ward, hospital and external services.”

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.

Adjusted to read
“…within the pilot site and to highlight any aspects of the intervention that needed to be improved all of which would inform the design and conduct of a future randomised controlled trial.”

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?

Some key headings have been added to this slightly expanded section to clarify the concept of complexity and ‘systems level’ as described by Sheill et al 2008. This now reads....
“Complex Interventions
Many interventions delivered within the stroke rehabilitation setting could be considered complex, though some are more complex than others, occurring at different points along what could be considered a spectrum of complexity (6). The degree of complexity might be gauged on the basis of the number of; components within the intervention (and the interactions between those components); actions required from participants; actions required from those delivering the intervention; organisational levels the intervention is targeting; and outcome measures employed (6). Others describe complexity at a systems level (14) urging careful consideration of the clinical context in which an intervention is delivered. In practice, both the intervention and the systems within which it operates are relevant thus the number of systems could also be considered in relation to the degree of complexity. For example, an OHC intervention is delivered to a patient, by staff operating as a team within a ward, which in turn is nested within a hospital which may be further supported by external specialist dental support services (as required). For the OHC intervention to work the intervention must function within and be supported by the team, ward, hospital and external services.

Researchers however have often strived to simplify research questions. Reducing variability in the participants, the intervention, the delivery and/or the context and introducing consistency across these parameters the aim was to increase internal and construct validity i.e. an efficacy study (15). However such a narrow approach to intervention evaluation comes at the expense of external validity. As a consequence, many evaluations of OHC interventions after stroke recruited very narrow patient populations, delivered very specific oral healthcare protocols which were implemented by specialist researchers or healthcare staff that were atypical within the normal clinical setting. As a result there are limitations on the clinical relevance of the study leading to delayed translation into clinical practice (15). In contrast, drawing on and accommodating the known components of complexity during the development and evaluation of an OHC intervention, informs the development of a clinical effectiveness study (15). Thus a clinically feasible, adaptable OHC intervention is delivered to a heterogeneous, clinically representative post stroke population within a typical stroke healthcare setting by a typical stroke rehabilitation team. Should it prove effective, capturing data on the interactions observed within and between components of the intervention, and the systems across which the intervention is delivered, will facilitate the translation of the research into practice (15; 16).”

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.

This statement was no longer appropriate within this section and has been removed.

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

Adjusted. Now reads ‘...we assessed the knowledge and attitudes of nursing staff immediately before and after this training component...’

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.

Adjusted to read “…Demonstrating one facet of complexity within the implementation of this complex OHC intervention, staff were not only part of the intervention but they were also participants. At the patient level they were responsible for the delivery of components of the OHC intervention to patients while at staff level they were in receipt of elements of the intervention.. “

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

Adjusted – see response to item 4 above.
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?

Adjusted to read “…Thus patients’ OHC was better supported than usual care (17).”

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?

Yes - now adjusted to read “…monitored throughout their stay on the ward.”

Results
11. Not sure what AG is?

Definition of this abbreviation (AG – Advisory Group) now appears earlier in the manuscript, within the methods section.

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

This section of the text has been revised to remove duplication between it 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.

Adjusted to read “…During this pilot we measured oral health related quality of life (GOHAI and the OHIP) and compared changes from the point of study recruitment over time.”

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?

We did intend to demonstrate our successful delivery of this complex intervention primarily by demonstrating the feasibility and impact of cascading interventions upon patient care. This whole section now includes some rewording to further clarify this and now reads...

“The main outcome of this study was the successful development and implementation of a highly complex OHC intervention. The benefits experienced at patient level relied upon the successful cascade of various components of the interventions through service, staff and patient levels of care. Service support impacted upon staff, and staff support in turn impacted upon nurses’ and clinical support workers’ ability to care for or assist patients to conduct independent OHC, all of which impacted upon patients’ oral health. Our mixed methods approach to evaluating the implementation of the complex intervention provided important complete and complementary evidence and guidance, invaluable in establishing the success of the delivery of the OHC intervention, informing refinements and our plans to design an evaluation of the effectiveness of the intervention using a randomised controlled trial design.”

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?

Adjusted to read “…Where possible, for data collection purposes, we would seek to ensure the trial received the support of the UK Stroke Research Network.”

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.”

Adjusted. Removed addition word and this now reads
“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.

Agreed – It would have been interesting and informative, but because of the limited funding available to support this work we were unable to follow-up patients after discharge.

18. 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?

Yes – some indication of a worsening of some scores. However, this was a small pilot and as a result was not designed to demonstrate the effectiveness of the OHC intervention so we should not place too much emphasis on these scores. As the pilot recruited patients from admission to the ward

19. 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??

Table 6 has been adjusted in light of the reviewer’s comments. Definitions for H/Hm are now included and the last two columns of data have been collapsed and are now presented within one. The location of interview should now be clearer to the reader, which was our intention in presenting this information.

**Discretionary revisions**

20. 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.

As a result of limited funding we were unable to assess the amount and quality of the OHC provided to patients within the pilot ward prior to introducing our study. We had recently conducted a comprehensive survey of OHC in Scottish Stroke Care settings (ref 17) and more recently a CSO funded qualitative focus group study of the beliefs and barriers to the provision of OHC in stroke care settings. From this information we felt we had an understanding of many of the main difficulties experienced by staff in the provision of OHC, the variability of OHC provision by different members of staff and the lack of support staff received (training, assessment tools, protocols, access to OHC equipment and products).

**Reviewer 2’s report**

**Main comments from Reviewer followed by response/action:**

**Major compulsory revisions:**

**Introduction**

21 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.

This reviewer’s comment conflicts with Reviewers 1 (and 4’s) comments that the introduction section was ‘.. well written and largely clear…’. This may perhaps reflect the two reviewers’ different levels of knowledge and familiarity with oral health care issues. We wrote this manuscript with the aim that it would be accessible to all with an interest in complex interventions. With this in mind, some detail is required in relation to the challenges posed by OHC research and previous research in the field. It was one of the main aims of the paper to expand upon the issue of complex interventions and their development and evaluation. As a result of Reviewer 1 and 4’s comments this has been expanded further.

**Methods:**

22. Could you please describe in some detail the content of the individual care plans?

The individual care plans within this study were developed in a pragmatic manner, independently by individual nursing staff (where required) for patients (as described in the methods section). The level of staff intervention ranged from a statement that the patient was capable of independent OHC to other patients that required fully
supported, high frequency OHC. Details included the frequency of care required, use of particular products or
equipment, involvement of family members etc. The protocol component of the experimental intervention aimed
to guide the development of these care plans. As we plan to evaluate the effectiveness of our intervention we do
not wish to publish details of the protocol at this point. Our main purpose in reporting this pilot stage was to
inform other researchers that are developing a complex intervention on one approach to development rather than
inform the provision of OHC in stroke care settings.

23. Nursing staff training. This is clearly important. Can you please describe how this was designed and
validated?

Further details of the development and design of the training session is now included in the methods section and
reads

“...Nursing staff received an OHC training session developed in conjunction with an experienced specialist
gerodontologist (PS) which aimed to consolidate their OHC knowledge, improve attitudes and heighten their
awareness of OHC issues. The training also reflected the expert AG’s recommendations relating to the ideal context
and nature of supporting patients’ OHC following stroke. We delivered our two hour training package to all nursing
staff across eight training sessions.”

24. Can you please describe how the individualised OHC was designed/developed by staff?

This was a highly pragmatic process based on nurses’ specialist training, the use of the assessment tool to
identify aspects of OHC that needed to be addressed and use of the protocols to develop the OHC. We did not
attempt to control this in any manner.

25. Outcome assessment. Can you please describe the training and levels of agreement/ accuracy for
outcome assessment i.e. dental/denture plaque.

The following text has been added to the methods section -
“The research assistant was trained in denture and dental plaque by an experienced gerodontologist and
a dental hygienist in an adult special care dentistry setting”
And further text to the results section –
“The agreement and accuracy for the outcome assessment for both the detail and denture plaque was
excellent. For both outcomes two raters analysed the same subjects. The kappa statistic for the dental
plaque inter-rater agreement is 0.90 (95% confidence interval 0.83 to 0.97), with a P-value for the test of
zero kappa being P=1.16 * 10^-42 and the corresponding kappa statistic for the denture plaque is 0.95 (95%
confidence interval 0.84 to 1.00), with a P-value for test of zero kappa being P=1.44 * 10^-14 (Table 2).”

Table 2
(a) Dental Plaque Training - Inter-rater reliability

<table>
<thead>
<tr>
<th>Dental Plaque</th>
<th>Rater 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt; 1/3</td>
</tr>
<tr>
<td>Rater 1</td>
<td>38</td>
</tr>
<tr>
<td>1/3-2/3</td>
<td>3</td>
</tr>
<tr>
<td>&gt;2/3</td>
<td>0</td>
</tr>
</tbody>
</table>

(b) Denture Plaque Training – Inter-rater reliability

<table>
<thead>
<tr>
<th>Denture plaque</th>
<th>Rater 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>None</td>
</tr>
<tr>
<td>Rater 1</td>
<td>6</td>
</tr>
<tr>
<td>Light</td>
<td>0</td>
</tr>
<tr>
<td>Moderate</td>
<td>0</td>
</tr>
<tr>
<td>Heavy</td>
<td>0</td>
</tr>
<tr>
<td>Very heavy</td>
<td>0</td>
</tr>
</tbody>
</table>

26. How was a diagnosis of chest infection made/validated?
We used the Mann criteria for chest infection and reference to this (ref 23) is included within the methods section
in the outcomes section.
27. Oral health related quality of life. Could you please explain/justify why two methods were employed i.e. GOHAI and OHIP.

The GOHAI and the OHIP capture slightly different aspects of oral health related quality of life (Locker et al 2001). We used both in the pilot study so that we could identify which measure to take forward to a main trial.

28. Statistical analysis.
   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.

Although the reviewer is correct that the raw plaque measures are not normally distributed, we would prefer to keep the parametric analysis for several reasons: (a) this is a pilot study with small sample sizes – so formal tests of normality would lack power. Therefore it could be falsely reassuring to get a non-significant P-value; and (b) we are implicitly looking at change scores i.e. within subject changes, or changes adjusted for baseline – this will tend to make the distribution more symmetric, regardless of the underlying distribution of the raw scores; and (c) the mean and standard deviation are still useful summary statistics, even when data are not symmetrically distributed (e.g. for economic analyses).

In respect of the best/worst scores, the value was felt to be that the worst score might be more indicative of the level of pain/discomfort and or low quality of life than say the customary measures of central tendency such as the mean or the median; whereas the best score might indicate what is achievable within an individual’s mouth in terms of a successful intervention – in the context of this exploratory pilot study it was felt worth giving these extreme values to see if they provided additional insights into how to capture what might be complex treatment effects.

Discussion.
29. ‘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.

Agreed. The use of foam swabs were not in fact included in the intervention (and instead were strongly discouraged) but some members of staff were very reluctant to stop using them. We shared the various recommendations not to use them in the provision of OHC were with the nursing staff but some members insisted they would continue to use them.

We have tried to make this clearer within the text by re-wording the section to “... While training both qualified nursing staff and clinical support workers from the pilot ward was seen as very important, some aspects of the intervention were not well received (marking names on dentures, using gauze covered fingers and suspending the use of foam swabs).”

Minor essential revisions.
Methods:
30. Service level intervention. The second sentence ‘We defined.... is long and its meaning is unclear.

Adjusted to shorten length an improve clarity to read “...We defined the local referral paths for patients admitted to the pilot ward requiring specialist dental support and communicated these arrangements to the ward staff. Referral arrangements differed between patients who were registered with a community dentist and those that were not and between patients with different dental needs (for example urgent and non-urgent)”.

Results
31. 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.
This was indeed the case. Members of staff continued to provide care for all patients admitted to the ward in which the pilot was being conducted. Patient consent was not required before staff could provide this basic care. In contrast, in order to use the patients’ data in the study or access their records for study purposes individual patient consent was required. This was the procedure as approved by the Scotland A Research Ethics committee.

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

We have reviewed this section and believe that this comment mainly related to the section of results reporting on Staff findings. These sentences have now been relocated to the methods section which now reads

“...Nursing staff received an OHC training session developed in conjunction with an experienced specialist gerodontologist (PS) which aimed to consolidate their OHC knowledge, improve attitudes and heighten their awareness of OHC issues. The training also reflected the expert AG’s recommendations relating to the ideal context and nature of supporting patients’ OHC following stroke. We delivered our two hour training package to all nursing staff across eight training sessions.”

33. Dental plaque data. Six quadrants – I guess you mean six ‘sextants’. This appears elsewhere. Adjusted as recommended.

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

Adjusted and now reads “…As teeth in any mouth are only as clean as the tooth with the most plaque “.

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

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

This section has now been adjusted in light of Reviewer 1’s comments above in item 14.

Implications for future research.
37. 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.

We found great benefit in employing a mixed methods approach to this pilot study but feel that the greatest benefit within this question of interest was to be gained at the pilot stage. The value of continuing to include a qualitative component within the main trial would, we believe, be far outweighed by the resource implications. The section within the implications for future research has been adjusted to now read “…trial design but because of the anticipated sample size required in our planned trial we believe there would be considerable resource implications to continue to use the mixed methods approach, as others have done (24). “

Discretionary revisions.
38. Table 4. Q1 seems to be missing.

Apologies for this numbering error. Adjusted to read Q1-12.

Reviewer 3’s report:

39. 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 “.
40. Page 8: More detailed description of the nature of the site (e.g., locale, type of patients seen, level of care provided) would be useful.

Some information relating to this was presented in the Methods section. This has now been expanded upon and reads:

“…Consecutive admissions to a mixed stroke ward (acute or rehabilitation patients) with a primary diagnosis of stroke over a 15 week period were approached to participate in the study. Adopting a pragmatic approach, dentition profile, age, communication ability and cognitive status were not exclusion criteria. In accordance with approval from the Scotland A Research and the local NHS Lanarkshire Ethics Committees, consent was sought from patients to access their medical notes and to measure their dental health and wellbeing.”

41. Page 11: There is considerable attrition of patient numbers from baseline to Time 2 in Table 3 (23 patients at baseline with 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.

We agree that the Time 2 column in what was Table 3 (now Table 4) is less than ideal and may cause confusion to the reader, since it averages the data at the visits 2, 3, 4 and 5. However in Tables 5 and 6, there were >30 responses at baseline, reducing to 15 at visit 1, 7 at visit 2, and then respectively 4, 1 and 1 at visits 3, 4 and 5. We did not want to exclude the very sparse data beyond visit 2 completely, but on the other hand it didn’t seem worth complicating the Table by reporting these visits separately. We have added a footnote giving these details of numbers of cases so averaged, and made it clear what the final column reports.

Adjustments: we have added the following paragraph to the discussion section:

“…As a result of our pilot we also established the rate of admission, retention and length of patient stay within the ward, the possible requirement for specialist dental services, the frequency of patients’ registration with community dentists and the need to monitor access to community dentists following discharge. Rate of discharge after stroke was much higher than initially anticipated. A relatively new Early Discharge team and evidence to support the effectiveness of community based rehabilitation (29) resulted in half of the patients with stroke being discharged within a week of their admission.”

42. 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 they were made clear that only the T-F and F-T answers enter into the statistical analysis involving McNemar’s test.

Adjusted. We now report all the questions 1-27 and 28-37 from the Knowledge and Attitude Questionnaire. This is a dilemma for the effective presentation of the results of an exploratory, pilot study. We don’t really think it is misleading as presented – we are clear that these are just the significant findings, and as such as summary of a larger set of analyses. There are equivalent disadvantages in presenting a vast number of underpowered exploratory analyses – the reader could well be overwhelmed with findings and not see what may be important signals to try to confirm in later studies. We have clarified that a McNemar test is based on the discordant values only.

Reviewer 4’s report

43. The authors do not discuss notions around “efficacy,” “effectiveness,” or “implementation” research which has received attention recently to increase the public health impact of interventions. Specifically, effectiveness research occurs in “real-world” settings (Glasgow & Emmons, 2007) but to influence public health, interventions found to be effective must be implemented well (Fixsen, Naoom, Blase, Friedman, & Wallace, 2005). Considering the environment where an intervention will be carried out -- such as when the intervention is
designed – is critical and is well illustrated by the study. The authors should consider where their
intervention stands on the efficacy - effectiveness – implementation continuum.

Reference to this literature is now included within the manuscript and additional methodological
information is also provided within the background section. In particular the following section has been
added to address the issues highlighted above.

“In contrast, drawing on and accommodating the known components of complexity during the development
and evaluation of an OHC intervention, informs the development of a clinical effectiveness study (15). Thus
a clinically feasible, adaptable OHC intervention is delivered to a heterogeneous, clinically representative
post stroke population within a typical stroke healthcare setting by a typical stroke rehabilitation team.
Should it prove effective, capturing data on the interactions observed within and between components of the
intervention, and the systems across which the intervention is delivered, will facilitate the translation of the
research into practice (15; 16)”.

44. The use of mixed methods
The rationale for using mixed methods should be more explicit (see (Tashakkori & Teddlie, 2008)
for a list of reasons for mixed methods). In general, the authors do not tap a now considerably
developed literature on mixed methods (Tashakkori & Teddlie, 2010).

We have now included a rational for using mixed methods design. In particular we have added the
following to the background section.

“To ensure the data we collected provided a complete picture of the implementation of the complex
intervention we used a mixed methods approach, with quantitative and qualitative approaches providing
complementary evidence (19).”

We also return to the issue within the discussion section and have added the following section -

“Mixed Methods Approach
By collecting both quantitative and qualitative data we were able to identify not only the aspects we
captured comprehensive and complementary evidence relating to the implementation of a complex
intervention that comprised of many components and interactions (anticipated and unanticipated) between
those components. For example...”

45. The authors state that they do not intend to use mixed methods in the next phase of the research.
While such an approach is standard, if resources permit they should reconsider that decision,
since in new sites with new providers and patients, new themes regarding the intervention design
(e.g., related to failure to carry through with the intervention) may continue to emerge.

A very valid point which we have taken onboard. We will consider the continued collection of qualitative
data perhaps within an exploratory trial thus capturing data from across a range of sites/settings to inform
translation.

46. The authors provide “quantitative” and “qualitative” findings within each level of the hierarchy.
This is an exemplary way to present the results although as they mention that a “standard”
approach would be to separate the two strands of the research. What they do not attempt is to
mix the methods at the level of the analysis. An example would be to examine the statements
made by providers or patients with low levels of knowledge about oral health, or among persons
whose knowledge does not improve over time.

We believe that we have mixed methods at the level of analysis. Some examples from the text are given
below...

a. “Although staff had access to a denture marking kit on the ward, ...Of 18 participants with dentures admitted
to the ward following a stroke, only six were named (Box B – Additional File: Staff and Patient Quotes).”

b. “We found no record of a referral to the MDT specifically for OHC related support, nor were any adaptive
tools or equipment (for example adapted handles for toothbrushes) issued to support participants’ resumption
of independent OHC during the pilot (Box C Additional File: Staff and Patient Quotes)”
48. In Tables 4 and 5 the numbers of patients over time are very small as are the differences in the item scores, but the p-values indicate high statistical significance. Perhaps a better strategy would be to simply show the data without statistical tests since the small sample size may lead to misleading p-values due to violations of the models upon with the p-values are based. Were the p-values based on exact methods?

We do not have strong feelings about this – our preference is to keep the P-values, which should be understood from the repeated statements about the pilot, exploratory nature of the study that such P-values are purely descriptive. Our experience is that if the P-values are removed they will be missed by some readers. The sample sizes are not that small – as indicated above, we have >30 subjects at baseline, and attrition of roughly 50% at each subsequent visit. In the full trial with considerably larger numbers and less missing data we will of course investigate whether the assumptions of the repeated measures models hold. The quoted P-values are from SAS PROC GENMOD, and as such will be asymptotic values.

**Plus the additional comments from the Trials associate editor:**

- Need to respond to referees comments in detail
  
  Adjusted.

- Need to incorporate all the supplementary tables into a single manuscript file

  Adjusted.

**References**