PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Methodological issues in the design and evaluation of supported communication for aphasia training: a cluster-controlled feasibility study
AUTHORS	Horton, Simon; Clark, Allan; Barton, Garry; Lane, Kathleen; Pomeroy, Valerie

VERSION 1 - REVIEW

REVIEWER	Ruth Herbert University of Sheffield, UK
REVIEW RETURNED	29-Feb-2016

GENERAL COMMENTS	This study evaluates the feasibility of training healthcare staff on stroke units in skills of supported communication. The motivation for the study is clear, as effective training is needed to ensure that people providing healthcare are able to communicate effectively with patients, and that patients undergoing healthcare are treated with dignity and are involved as far as is possible in information and decisions about their care. Communication training already forms part of basic training for most of MDT professional groups, but the skilled communication required by staff to enable them to communicate effectively with people with aphasia requires additional knowledge and skills. I think that research into this area is warranted but I am not convinced that this design and method has revealed any new insights. I am also not convinced that the feasibility of implementing this training in this setting has been demonstrated. The reasons for this are outlined below followed by specific points relating to the text. The difficulties inherent in the process of attempting to train staff within the workplace are well documented in terms of difficulties in ensuring staff attendance at training, and lack of carryover of training to real settings. The authors found evidence of these, and acknowledge this openly, stating as one example that they excluded junior doctors from the study as their shift patterns meant the training was not possible for them. They also state that 70 staff were recruited and 28 completed the training. As one aim of a feasibility study is to identify participants' compliance or adherence to the intervention, this evidence suggests the training is not feasible. Hence a full trial is perhaps not indicated. Further to this, most of the patients were not eligible as they 'lacked capacity' or were too unwell. Again this raises questions about the feasibility, as the training addressed needs for only a minority of patients. It is perhaps the case that this training is better suited to later in the care pathway. Many nurse training courses integrate communication training into

	their curriculum, and that seems the most effective and sensible means of ensuring that future workforce have the necessary communication skills. It is known that communication training is needed, and it is known that it will be partially effective in the setting described here. I think a major trial is probably not indicated as the same issues will emerge – people failing to attend training, and failing to adapt working practices in sufficient numbers to make a difference to patients' experiences. Hence I think it would be appropriate for the authors to consider their outcomes, and reflect on what the data indicate in terms of future actions. In my opinion the data point to identifying alternative forms of communication training, for example those which are more embedded in basic training and require trainees to pass modules, and to demonstrate competencies. I think the study could be easily redrafted to recognize this and this would be a strong and important message. ABSTRACT The authors report 'poor completion rates' for patients so data is missing from the study and later state they cannot make power calculations due presumably to this problem in data collection. This suggests again that a future trial is not indicated. The abstract ends with 'modifications are needed before definitive cluster randomized trial can be carried out' but needs to identify what these are. The name of the intervention is not clear – it is very long and wordy and not recognizable as a 'product' to be trialled. The abstract identifies a range of difficulties with implementation and adherence, cites the low numbers recruited and completed, recognizes loss of data, yet concludes that a future trial is indicated. I think the evidence suggests that a future trial is not indicated INTRODUCTION P5 LL39-53 The definition of supported communication is not clear and needs to state more carefully what the intervention entails. For example it refers to interacting components then cites staff training as an example of this. For an approach to be examined it needs to be very clear what it consists of. I am not sure also why it says that a range of behaviours is required from patients. I don't think these are easy to demand especially in acute settings. This seems to me to be the fixed entity, and it is the environment around the patient including the staff, that needs to adapt to the reality of the patient's difficulties. This is a strong motivation for this study so could be more strongly expressed. P6 LL 12-18 Refers to 'more recently ' findings from studies of nurse training but the cited works are from long ago. METHODS The methodology including a range of forms of data collection are appropriate for this type of investigation.

	Inclusion criteria I am unsure about the rationale for excluding people with mild aphasia. The rationale for exclusion – they don't benefit from this form of approach – comes from one study, looking at people later on in recovery and with their conversation partners. Many people with more mild forms of aphasia do report difficulties communicating with staff in the early days post stroke. The PPI details seem clear and appropriate and the development of the training was carried out collaboratively to ensure acceptability. The outcome measures for aphasia include the SAQOL 39 which is a linguistically demanding assessment and I wonder if the moderate and severe people who took part could really access this assessment. RESULTS The issue regarding recruitment and retention of patients through the study is clearly demonstrated in the flow diagram which again argues against taking this research further. The same issue arises with staff recruitment with few people taking part in the training and fewer completing this. Numbers are inconsistent with 3 control and 28 intervention staff attending training. Unclear what the control group were being trained to do. The study later reports that 17/37 staff completed learning logs but it is not clear whether these 37 staff attended training or not. It is not clear why they would report a learning log if they hadn't attended training but only 28 intervention staff were trained. SAQOL data. The authors need to clarify whether positive reports are high or low scores. There are too many data points in the Table 4 and this should be reduced to clarify the main findings. I cannot see what these are at present. CAMS data. Similar to the above. It is not clear what is a positive finding and there are far too many data points. TOMS data are not reported for the participants in the study but for the site as a whole and it is not clear why this is the case. Presumably these people had not consented to take part in the study but this needs clarification. Economic evaluation reports cost of training per participant and refers to 13 intervention participants – It is unclear whether this refers to staff or patients, and this does not match numbers cited previously. Discussion P23 LL10-12 "We demonstrated the feasibility of recruiting staff to control and intervention conditions, and of delivering SC training to a multidisciplinary stroke team." I am afraid that I disagree with this summary statement and suggest that this study has failed to demonstrate feasibility. I think the

	lessons learned from the study are invaluable and these could be reported fully in a more targeted fashion to inform future attempts at such training. I am afraid also that I am at a loss as to why the control arm were also getting the training so this needs clarification throughout.

REVIEWER	Erin Godecke Edith Cowan University, Perth, Western Australia, Australia
REVIEW RETURNED	08-Mar-2016

GENERAL COMMENTS	More discussion regarding the differences in LOS at baseline for the units and what might contribute to that. Page 2 Line 25 – line from '18 …6 month follow up.' Should go in results section Page 2 Line 52 – Suggest adding text to explain how 'acceptable' was measured. Page 5 Lines 14-21 Mixed tense in this sentence needs to be corrected. Page 6 Line 34 - Suggest replacing aphasic patients with 'people with aphasia' Page 6 Line 57 - Need to add 'early after stroke' or some reference to the timepoint that this study refers to. Page 9 Line 9 Need to add the TOMS domain for the aphasia score eg impairment Page 9 Line 23 Need to add how people with severe aphasia were consented. Page 11 Line 53 Sentence doesn't make sense. Page

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Ruth Herbert
Institution and Country: University of Sheffield, UK
Competing Interests: None declared

Thank you for this review and the opportunity to respond to the points made. The purpose of this study was to examine the feasibility of conducting a subsequent definitive trial of stroke service staff training to provide supported communication for aphasia in a post-acute stroke setting (vs usual care). We have set out to report our findings and conclusions as transparently and explicitly as possible. We would argue that the study has provided a number of new insights (e.g. regarding barriers and facilitators to recruitment of staff and patients; outcome measures; model of training; potential for use of routine data). The reviewer herself say that "lessons learned from the study are invaluable". The point made about alternative forms of communication training is an interesting one, and worthy of study, but this was not the purpose of the current study.

We have not claimed that it is feasible to undertake a subsequent trial without addressing a number of design issues, which are set out in the Conclusions (main text), where we consider outcomes and reflect on future actions. We have obviously not got our message across sufficiently clearly. We have therefore sought to clarify a number of points through revisions to the text, which are set out in the

responses below.

ABSTRACT
The authors report ‘poor completion rates’ for patients so data is missing from the study and later state they cannot make power calculations due presumably to this problem in data collection. This suggests again that a future trial is not indicated.
The abstract ends with ‘modifications are needed before definitive cluster randomized trial can be carried out’ but needs to identify what these are.

Response
We feel that we have clearly stated in both the Abstract and Conclusions to the main paper that modifications are required. In the Abstract we have amended the wording in ‘Conclusions’ to be as explicit as possible within the word-count restrictions. (“Modifications to the design are needed before a definitive cluster-randomized trial can be undertaken.”)

The name of the intervention is not clear – it is very long and wordy and not recognizable as a ‘product’ to be trialled.

Response
We have stated that the intervention is “supported communication for aphasia training, adapted to the stroke unit context” – we feel that it is necessary to state that the training is adapted to the ‘stroke unit context’, due to its origins in community settings with volunteers. We have amended the text under Objectives in the Abstract to be less wordy: “To assess the feasibility and acceptability of training stroke service staff to provide supported communication for people with moderate-severe aphasia in the acute phase”

The abstract identifies a range of difficulties with implementation and adherence, cites the low numbers recruited and completed, recognizes loss of data, yet concludes that a future trial is indicated. I think the evidence suggests that a future trial is not indicated

Response
We argue that we have been very clear in stating that before any future trial is undertaken, a number of methodological / design issues have to be addressed. To ensure there is no ambiguity we have amended the text in ‘Strengths and Limitations’ overview as follows: “Valuable insights gained into components of the intervention and its implementation will enable us to make necessary adjustments to the study design if a future in a future trial is undertaken.”

INTRODUCTION
P5 LL39-53
The definition of supported communication is not clear and needs to state more carefully what the intervention entails. For example it refers to interacting components then cites staff training as an example of this. For an approach to be examined it needs to be very clear what it consists of. I am not sure also why it says that a range of behaviours is required from patients. I don’t think these are easy to demand especially in acute settings. This seems to me to be the fixed entity, and it is the environment around the patient including the staff, that needs to adapt to the reality of the patient’s difficulties. This is a strong motivation for this study so could be more strongly expressed.

Response

We have chosen to provide a complete description of the intervention (supported communication) in the Methods section (Interventions). In addition, Supplementary File 1 provides all the training content in the form of a set of PowerPoint slides. If required we can move the exact specification of the intervention to the Introduction. We have made a small change to the text to highlight the need for adaptations to usual communication practices: "…jointly responsible for achieving exchange of information and sustaining participation through adaptations to usual communication practices, for example the use of appropriately phrased questions, extra time or low-tech resources (e.g. pen and paper)."
In the Introduction we have discussed the principles of supported communication and also set out our perspectives on supported communication for aphasia training as a complex intervention. In terms of understanding the intervention, the mechanisms underlying its effects, and the feasibility of designing a study to test the efficacy of such an intervention, we feel that it is important to highlight complexity. We need to be able to show the lack of a simple one-to-one relationship between intervention and outcomes, the potential problems for evaluators, and the practical and methodological difficulties that need to be overcome. For example, staff are trained, but must also implement new skills in day-to-day practice in unpredictable ways and in an unpredictable range of contexts; patients may respond in any number of ways ("a range of behaviours") because communication is interactive and context dependent. These considerations all drove the design and conduct of the study and have informed our interpretation of the findings.

P6 LL 12-18
Refers to 'more recently' findings from studies of nurse training but the cited works are from long ago.

Response
'More recently' here means 'more recently than the SR of 2010; one paper (Jensen et al) is 2015; the other (McGilton et al) is 2011

METHODS
The methodology including a range of forms of data collection are appropriate for this type of investigation.
Inclusion criteria. I am unsure about the rationale for excluding people with mild aphasia. The rationale for exclusion – they don't benefit from this form of approach – comes from one study, looking at people later on in recovery and with their conversation partners. Many people with more mild forms of aphasia do report difficulties communicating with staff in the early days post stroke.

Response
This is an interesting point. We relied on best evidence available to make this decision and have stated the reasoning behind this choice, making reference to the Kagan et al study as justification.

The PPI details seem clear and appropriate and the development of the training was carried out collaboratively to ensure acceptability.The outcome measures for aphasia include the SAQOL 39 which is a linguistically demanding assessment and I wonder if the moderate and severe people who took part could really access this assessment.

Response
This is an interesting point; the SAQOL-39g was chosen as being specifically designed for people with aphasia and with robust psychometric properties. In the Discussion (Outcome measures) section we do point out that using such PROMs "…may place a high burden on patients' time or emotional resources during in-patient episodes…". The measures were administered by researchers who were

able to explain items and to pace the data collection sessions as necessary.

RESULTS
The issue regarding recruitment and retention of patients through the study is clearly demonstrated in the flow diagram which again argues against taking this research further.

Response
We have pointed out and discussed the problems with patient participant recruitment, proposing and discussing alternative approaches which are suggested by findings from this study.

The same issue arises with staff recruitment with few people taking part in the training and fewer completing this. Numbers are inconsistent with 3 control and 28 intervention staff attending training.

Response
We argue that although staff recruitment rates were slower than projected at both sites, recruitment was to target, and we were able to recruit staff to make up for attrition at both sites. At the intervention site we trained more staff (N=28) in Supported Communication than was required in the Protocol (N=24); at the control site, as pointed out in the Discussion ('Strengths and limitations'; 'Recruitment & training of staff' sections) few staff were trained, reflecting the pragmatic nature of the trial i.e. provision of training was entirely dependent on local circumstances (e.g. SLT / staff availability and time etc.).

Unclear what the control group were being trained to do.

Response
We have made the following changes to the text (Methods; Control intervention): "…stroke staff education for patients' communication needs as recommended in clinical guidelines. 9, 26 Training in working communication with people with aphasia on the control unit was individualized to specific staff and patient needs at the clinical team's discretion, and carried out 'hands-on' in routine clinical practice settings."

The study later reports that 17/37 staff completed learning logs but it is not clear whether these 37 staff attended training or not. It is not clear why they would report a learning log if they hadn't attended training but only 28 intervention staff were trained.

Response
We have expressed this as a conservative report of proportion of N staff completing logs compared with N recruited overall. We can amend to '17 of the 28 staff trained in the intervention [61%]…' if required.

SAQOL data. The authors need to clarify whether positive reports are high or low scores. There are too many data points in the Table 4 and this should be reduced to clarify the main findings. I cannot see what these are at present.

Response
Higher scores indicate more positive outcomes – this information has been added as a footnote to Table 4

Part of the feasibility of this trial was to assess which outcomes should be used for the main trial so we have tried to report as much information as possible about the outcome measures. Hence we have kept the table as it is.

CAMS data. Similar to the above. It is not clear what is a positive finding and there are far too many data points.

Response
Higher scores indicate more positive outcomes – this information has been added as a footnote to Table 5.
As is the case for SAQOL-39g part of the feasibility of this trial was to assess which outcomes should be used for the main trial so we have tried to report as much information as possible about the outcome measures. There is no overall scale for CAMS3; all the items are important to understand how the intervention might be improved if a full trial was warranted. Hence we have kept the table as it is.

TOMS data are not reported for the participants in the study but for the site as a whole and it is not clear why this is the case. Presumably these people had not consented to take part in the study but this needs clarification.

Response
The TOMS data are from a routinely collected measure for both of these centers and we have used it for ease of comparison between the units.

Economic evaluation reports cost of training per participant and refers to 13 intervention participants – It is unclear whether this refers to staff or patients, and this does not match numbers cited previously.

Response
We have changed the text in Results (Economic evaluation) as follows: “The training cost amounted to £560.37 per participant when apportioned across the 13 intervention participants who provided consent for the intervention. This was considered a conservative approach as we did not wish to underestimate such costs.”
We have also highlighted the distinction between patients recruited to intervention and control sites in Results (‘Patient recruitment and retention’): “20 (42.5%) consented to participate (13 intervention; 7 control);”.

Discussion
P23 LL10-12
“We demonstrated the feasibility of recruiting staff to control and intervention conditions, and of delivering SC training to a multidisciplinary stroke team.” I am afraid that I disagree with this summary statement and suggest that this study has failed to demonstrate feasibility. I think the lessons learned from the study are invaluable and these could be reported fully in a more targeted fashion to inform future attempts at such training.

Response
We have distinguished statements about the feasibility of different aspects of the trial. Thus, here we feel we are justified in arguing that it is feasible to recruit to intervention and control sites; and to train a multidisciplinary staff team in the experimental intervention. Elsewhere we state that a number of

other matters require consideration and modification. We have changed the text thus in Conclusions: "The study has highlighted issues that require consideration and modification before feasibility can be confirmed and a subsequent trial undertaken:"

I am afraid also that I am at a loss as to why the control arm were also getting the training so this needs clarification throughout.

Response
Staff in the control arm were receiving 'usual training' as well as any additional input that was considered appropriate by the clinical team as befits a pragmatic trial. Intervention training was very specific (as described in the paper and supplementary file) and was not provided to staff in the control arm.

Reviewer: 2
Reviewer Name: Erin Godecke
Institution and Country: Edith Cowan University, Perth, Western Australia, Australia
Competing Interests: None declared

Thank you for this review and the opportunity to respond to the points made.

More discussion regarding the differences in LOS at baseline for the units and what might contribute to that.

Response
The text has been changed as follows (Discussion; Strengths and limitations): "Pre-trial anonymised clinical data showing higher 'length of stay on previous (acute) unit' for intervention patients are open to a number of interpretations – for example, differences in local practices; location of acute and rehabilitation units; patients with greater recovery on admission to the rehabilitation unit. However no other measures suggested systematic differences in patients admitted to the two units. On the other hand, anonymised data collected during the trial show significant differences in TOMS admission scores (table 3) between units…"

Page 2 Line 25 – line from '18 …6 month follow up.' Should go in results section

Response
Text moved to Results section of the Abstract

Page 2 Line 52 – Suggest adding text to explain how 'acceptable' was measured.

Response
Abstract, Results, text added: "Training in the intervention was carried out with 28 staff and was found to be acceptable in qualitative reports."

Page 5 Lines 14-21 Mixed tense in this sentence needs to be corrected.

Response
Corrected: “Effective communication is essential to maintaining patient safety, (REF) ensuring a good experience of care, (REF) and providing the basis for therapeutic engagement…”

Page 6 Line 34 - Suggest replacing aphasic patients with ‘people with aphasia’

Response
Changed as suggested

Page 6 Line 57 - Need to add ‘early after stroke’ or some reference to the timepoint that this study refers to.

Response
Changed as suggested: “the feasibility of conducting a subsequent trial of supported communication training for patients early after stroke in mutlidisciplinary stroke teams. “

Page 9 Line 9 Need to add the TOMS domain for the aphasia score eg impairment

Response
Added

Page 9 Line 23 Need to add how people with severe aphasia were consented.

Response
Clarified thus: “Able to give informed written or witnessed oral consent as judged by an SLT or other qualified member of the clinical team (e.g. OT; Clinical Psychologist).”

Page 11 Line 53 Sentence doesn’t make sense.

Response
Re-written thus: “The patient outcomes SAQOL-39g and EQ-5DL were compared between the control and intervention groups at baseline, discharge and 6-month follow-up; CAMS3 was compared only at discharge”