PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	A feasibility study of an integrated stroke self-management programme: a cluster randomised controlled trial
AUTHORS	Jones, Fiona; Gage, Heather; Drummond, Avril; Bhalla, Ajay; Grant, Robert; Lennon, Sheila; McKevitt, Christopher; Riazi, Afsane; Liston, Matthew

VERSION 1 - REVIEW

REVIEWER	Lisa Kidd Glasgow Caledonian University, Glasgow, UK
REVIEW RETURNED	21-Jul-2015

GENERAL COMMENTS	Many thanks for inviting me to review this paper. The paper is generally well written and describes a well conducted feasibility study which has significant potential impact in shaping the direction of future stroke self-management research and practice. I have only minor comments and requests for clarifications. Page 5, lines 35-36: what is level 1 evidence? Explain this here. Page 6: can you clarify or add a couple of sentences to describe what current CSR consists of? Page 10, lines 45-48: were the “seven predetermined strategies” the same as the seven principles listed in Table 1 – please clarify. Page 11 – Recruitment section: can you add something to describe how soon after diagnosis patients were recruited to begin CSR? Did this vary between sites? Might it influence the findings at all? Page 18, line 20: I wasn’t clear what you meant by ‘post stroke onset’ – does this mean the time between stroke occurring and symptom onset/stroke diagnosis? Or do you mean time between stroke diagnosis and start of CSR programme? Please clarify. Page 24, line 3: the authors comment that one of the sites had a ‘proportionately higher use of therapy assistants in the lower resource use group’. This begs the question and is worth clarifying, whether the composition of the CSR teams differed between sites and this should be taken into consideration within the findings and their implications for a future trial/implementation in practice. Page 29, lines 10-14: the authors comment that “at least 18 clusters would be required recruiting 20 participants per site to evaluate the effectiveness of this stroke SMP in a full trial.” Can the authors

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	comment on the feasibility of this in a larger trial and expectations in terms of time to recruit given the challenges noted in this feasibility study of clinician turnaround and potential restructuring of services? Figure 1: there are missing numbers for participants in the 'not eligible for study' box and 'withdrawal' is misspelt throughout the figure. Appendix: It was really useful to include the CONSORT reporting guidelines. I wonder whether it might also be useful to include the TIDiER checklist as a way to more fully describe the intervention itself. A few typos and grammatical errors to note.

REVIEWER	Dr Monique Kilkenny Translational Public Health and Evaluation Division Stroke and Ageing Research Centre Department of Medicine School of Clinical Sciences at Monash Health Monash University
REVIEW RETURNED	23-Jul-2015

GENERAL COMMENTS	1. Abstract: Intervention: What does co-produced mean? 2. Abstract: Main outcome measures: Please be consistent with timing of assessment measures 12 weeks (main manuscript) or 3 months (abstract) 3. Abstract: Results: please report the 95% CI between the arms of the trial 4. Abstract: Conclusion: What does pre-determined criteria mean? 5. Methods: Selection of sites: Of the 21 CSR teams who met eligibility criteria: How many agreed? How many were selected? How many teams who met eligibility criteria were from various locations (e.g. metropolitan versus rural) or socioeconomic status (e.g. lower versus higher)? 6. Methods: Recruitment: What does a two-stage command mean? Please provide a reference 7. Methods: Recruitment: Please check language and rewrite lasts sentence in first paragraph "Exclusion criteria for communication level…" 8. Is this feasibility study a Phase I or II trial? 9. Results: Intervention fidelity: 3rd paragraph: What were the types of clinicians (n=34)? 10. Results: Recruitment rates: spelling errors ..exluded should be excluded…recrutment should be recruitment 11. Results: Recruitment rates: bracket missing…(at a rate of 5.57/ month 12. Results: Recruitment rates: Why were patients with cognitive and communication impairments ineligible to participate? 13. Figure 1: Difficult to read ..please make font larger 14. Results: Randomisation: Participant characteristics: Please do not repeat results in the results section as well as a Table e.g. post stroke onset 15. Results: Randomisation: Participant characteristics. Please provide data for the last sentence (e.g. % intervention and % control)..”there was no significant difference between the study arms for this (p=0.35).” 16. Table 2 add an extra column for p-values to show whether there

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	was differences between the two arms of feasibility study (control and intervention). Please provide % for values in column 2 and 3. 17. For values in Table 2 were they normally distributed? If not normal, please present median values and 25th and 75th percentiles. 18. Table 3 difficult to read..split over 2 pages.. 19. Table 3: Were values adjusted for cluster in the multi-level model? Please provide all outcome data for each assessment (baseline, 6 weeks and 12 weeks).

REVIEWER	Dr Yannan Jiang The University of Auckland New Zealand
REVIEW RETURNED	02-Aug-2015

GENERAL COMMENTS	This is a pilot cluster randomised trial to test the feasbility of conducting a definitive trial into the effectiveness of a self-management progamme integrated into stroke rehabilitation. Four stroke rehabilitation teams were randomised with 78 eligible patients recruited to the study. Patients' quality of life, self-efficacy, functional capacity and health and social care utilisation were measured at baseline, 6 and 12 weeks. Fidelity and acceptability of the delivery was also evaluated. ABSTRACT: Scheduled visits should be reported consistently, e.g. three months = 12 weeks? The results section needs to be revised. The proportion of 24.6% was calculated as the numbers recruited divided by the numbers referred, which may be more approprate to divide by the number of patients who met trial eligibllity criteria (78/138=56.5%). Was this low recruitment rate due to patient consent? Also, 95% CIs were not reported properly (no value attached to outcomes) and not required for frequencies and percentages. The p-value was not informative when estimated treatment effect was not reported for any outcome measure. The conclusions should be more conservative and supported by the results presented in the abstract. For example, minimal data was lost to follow up was based on a 85% completion rate. Cost-effectivenss analysis was reported as "costs varied by site" with no further information. METHOD: Ethical approval should be mentioned first. Randomisation was relatively straightforward with only four clusters to be randomised. Was simple randomisation conducted at 1:1 ratio without matching? For sample size, was recruitment target set for individual stroke rehabilitation team as a cluster randomised trial? On page 12, the authors stated that "participants' age, sex, social support, socioeconomic status and past medical history were described and compared between groups to test randomisation". Shouldn't this comparison be at the cluster level? Since this is a feasibility study, the statistical analysis should focus more on descriptive summaries at the cluster and patient levels than any tests that could be underpowered. Reason for age adjustment was not given, and intracluster correlation coefficient (ICC) was not estimated which is an important information for sample size calculation in cluster randomised trials. RESULTS: Confidence intervals are not required for recruitment rates. Minor typos are to be checked and corrected .The flow

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	diagram should follow suggested format for cluster randomised trials, please refer to "Consort 2010 statement: extension to cluster randomised trials". Baseline characteristics need to be reported at both cluster and individual participant levels. With the nature of the feasbility study aiming for collecting necessary data for a definitive trial, descriptive statistics are more informative than statistical tests. For clinical outcomes both means and standard deviations should be reported at scheduled visits by treatment groups, and if important, change from baseline to 6 and 12 weeks. Intracluster correlation coeffcients for important outcomes need to be estimated. With only four clusters in the feasbility study, assuming ICC=0 in sample size calculation for a definitive trial is not justified. Cost-effective analysis may require review from an economist. The CONSORT checklist needs to follow the extension for cluster designs, as stated in the footnote.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name Lisa Kidd
Institution and Country Glasgow Caledonian University, Glasgow, UK
Please state any competing interests or state ‘None declared’: none.

Please leave your comments for the authors below
Many thanks for inviting me to review this paper. The paper is generally well written and describes a well conducted feasibility study which has significant potential impact in shaping the direction of future stroke self-management research and practice. I have only minor comments and requests for clarifications.

Page 5, lines 35-36: what is level 1 evidence? Explain this here.

The reference to the term ‘level 1’ has now been omitted and replaced with evidence from systematic reviews

Page 6: can you clarify or add a couple of sentences to describe what current CSR consists of?

We have added a sentence to clarify who delivers community stroke rehabilitation and where.

Page 10, lines 45-48: were the “seven predetermined strategies” the same as the seven principles listed in Table 1 – please clarify.

We apologise for this inconsistency- We have now used ‘seven principles’ consistently throughout the document

Page 11 – Recruitment section: can you add something to describe how soon after diagnosis patients were recruited to begin CSR? Did this vary between sites? Might it influence the findings at all?

Thank you, We have clarified that all participants were recruited within 2 weeks of referral to CSR

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Page 18, line 20: I wasn't clear what you meant by 'post stroke onset' – does this mean the time between stroke occurring and symptom onset/stroke diagnosis? Or do you mean time between stroke diagnosis and start of CSR programme? Please clarify.

This has now been clarified to explain we meant length of time since stroke onset

Page 24, line 3: the authors comment that one of the sites had a 'proportionately higher use of therapy assistants in the lower resource use group'. This begs the question and is worth clarifying, whether the composition of the CSR teams differed between sites and this should be taken into consideration within the findings and their implications for a future trial/implementation in practice.

Thank you for this recommendation we have added a sentence in the discussion to highlight the need for future studies to consider composition of community teams i.e. the ratio of professional versus support staff

Page 29, lines 10-14: the authors comment that "at least 18 clusters would be required recruiting 20 participants per site to evaluate the effectiveness of this stroke SMP in a full trial." Can the authors comment on the feasibility of this in a larger trial and expectations in terms of time to recruit given the challenges noted in this feasibility study of clinician turnaround and potential restructuring of services?

Thank you for this observation- we have now added a sentence in the discussion to address the points noted

Figure 1: there are missing numbers for participants in the 'not eligible for study' box and 'withdrawal' is misspelt throughout the figure.

We apologise for this and have revised Figure 1, also to reflect the cluster RCT format as advised by Reviewer 3.

Appendix: It was really useful to include the CONSORT reporting guidelines. I wonder whether it might also be useful to include the TIDiER checklist as a way to more fully describe the intervention itself.

We have now included the TIDiER checklist

A few typos and grammatical errors to note.

We have proof read again and we hope there are no more errors within the revised document.

Reviewer: 2

Reviewer Name Dr Monique Kilkenny
Institution and Country Translational Public Health and Evaluation Division
Stroke and Ageing Research Centre
Department of Medicine
School of Clinical Sciences at Monash Health
Monash University
Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below
1. Abstract: Intervention: What does co-produced mean?

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Thank you, to avoid any misunderstanding this term has now been removed

2. Abstract: Main outcome measures: Please be consistent with timing of assessment measures 12 weeks (main manuscript) or 3 months (abstract)

Three months has been changed to 12 weeks
3. Abstract: Results: please report the 95% CI between the arms of the trial

We are not sure we fully understand, as this was in the original manuscript but has been taken out in response to reviewer 3's comments.

4. Abstract: Conclusion: What does pre-determined criteria mean?

We have now changed this terminology to 'key principles'

5. Methods: Selection of sites: Of the 21 CSR teams who met eligibility criteria: How many agreed? How many were selected? How many teams who met eligibility criteria were from various locations (e.g. metropolitan versus rural) or socioeconomic status (e.g. lower versus higher)?

A sentence has been added to clarify number of teams who agreed to participate, and setting of those teams selected.

6. Methods: Recruitment: What does a two-stage command mean? Please provide a reference

We have now clarified what is meant by these criteria and linked the sentence to a supporting reference.

7. Methods: Recruitment: Please check language and rewrite lasts sentence in first paragraph "Exclusion criteria for communication level…"

This sentence has now been amended.

8. Is this feasibility study a Phase I or II trial?

We would like to clarify that the study is a feasibility trial and follows the descriptors advocated in the MRC framework for research into complex interventions.

9. Results: Intervention fidelity: 3rd paragraph: What were the types of clinicians (n=34)?

We have added a sentence to clarify that clinicians from all professionals and support workers took part in the focus groups.

10. Results: Recruitment rates: spelling errors ..exluded should be excluded…recrutment should be recruitment

Amended with thanks

11. Results: Recruitment rates: bracket missing…(at a rate of 5.57/ month

Amended with thanks

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12. Results: Recruitment rates: Why were patients with cognitive and communication impairments ineligible to participate?

Thank you for highlighting this point. We have added further explanation in the main text (page 16). Patients with cognitive and communication impairments were screened out if unable to follow a verbal or non-verbal two-stage command. This was set as an eligibility requirement as the intervention is based on cognitive interaction between practitioner and stroke survivor, and so requires a certain minimum level of cognitive and communication ability.

13. Figure 1: Difficult to read ..please make font larger

We apologise for this formatting error and have revised Figure 1, also to reflect the cluster RCT format as advised by Reviewer 3.

14. Results: Randomisation: Participant characteristics: Please do not repeat results in the results section as well as a Table e.g. post stroke onset

We have removed the duplicated data in the main text.

15. Results: Randomisation: Participant characteristics. Please provide data for the last sentence (e.g. % intervention and % control)..”there was no significant difference between the study arms for this (p=0.35).”

We have added the relevant data. Baseline assessments were completed by 39 (98%) out of 40 participants in the intervention arm, and 35 (92%) out of 38 participants in the control arm.

16. Table 2 add an extra column for p-values to show whether there was differences between the two arms of feasibility study (control and intervention). Please provide % for values in column 2 and 3.

We thank the reviewer for highlighting this point, and have added percentages for values in columns 2 and 3. With respect to p-values for comparing the control and intervention arms of the study, we would prefer to omit these, in line with the recommendation provided by the CONSORT statement (http://www.consort-statement.org/checklists/view/32-consort/510-baseline-data), which discourages the use of significance tests for baseline data as superfluous; rather, the size of any imbalances between groups and the potential prognostic strength of these data should be considered, which we did in our study by adjusting for the unbalanced factor age in the statistical analysis model.

17. For values in Table 2 were they normally distributed? If not normal, please present median values and 25th and 75th percentiles.

Time post stroke onset was not normally distributed so we have provided this data as median and interquartile ranges. We can confirm that all other clinical data were normally distributed but for mild floor and ceiling effects for SSEQ, SAQOL and HAD. Given the reasonable sample size this supported our decision to use parametric statistics

18. Table 3 difficult to read..split over 2 pages..

We apologise for this and have adjusted the positioning of Table 3.

19. Table 3: Were values adjusted for cluster in the multi-level model?

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Please provide all outcome data for each assessment (baseline, 6 weeks and 12 weeks).

Yes, the multi-level model used was adjusted for cluster. We have added means and standard deviations to Table 3 for each time point.

Reviewer: 3

Reviewer Name Dr Yannan Jiang
Institution and Country The University of Auckland
New Zealand
Please state any competing interests or state ‘None declared’: None declared

Please leave your comments for the authors below
This is a pilot cluster randomised trial to test the feasbility of conducting a definitive trial into the effectiveness of a self-management progamme integrated into stroke rehabilitation. Four stroke rehabilitation teams were randomised with 78 eligible patients recruited to the study. Patients' quality of life, self-efficacy, functional capacity and health and social care utilisation were measured at baseline, 6 and 12 weeks. Fidelity and acceptability of the delivery was also evaluated.

ABSTRACT: Scheduled visits should be reported consistently, e.g. three months = 12 weeks? The results section needs to be revised.

We apologise and have amended the abstract.

The proportion of 24.6% was calculated as the numbers recruited divided by the numbers referred, which may be more approprate to divide by the number of patients who met trial eligibllity criteria (78/138=56.5%). Was this low recruitment rate due to patient consent?

Thank you for highlighting this, and we have amended the percentage figure in the abstract. The recruitment rate was indeed due to 60 participants declining study participation. This figure is included in the study flow diagram in Figure 1.

Also, 95% CIs were not reported properly (no value attached to outcomes) and not required for frequencies and percentages. The p-value was not informative when estimated treatment effect was not reported for any outcome measure.

Thank you; we have corrected the sentence in the abstract to clarify.
The conclusions should be more conservative and supported by the results presented in the abstract. For example, minimal data was lost to follow up was based on a 85% completion rate. Cost-effectiveness analysis was reported as "costs varied by site" with no further information.

The concluding sentence has been reworded more conservatively

METHOD: Ethical approval should be mentioned first.

We moved the “Ethical approval” section to follow the “Design” section in the Methods.

Randomisation was relatively straightforward with only four clusters to be randomised. Was simple randomisation conducted at 1:1 ratio without matching?

Thank you; we have adopted your useful wording.

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For sample size, was recruitment target set for individual stroke rehabilitation team as a cluster randomised trial?

The recruitment target for this feasibility study was 80 participants across all sites. The intention was to recruit relatively evenly from all sites; however, no individual recruitment target was set for each cluster, in order to maximise efficiency, which resulted in recruitment of 16/24/22/16 participants from the 4 individual clusters (Figure 1).

On page 12, the authors stated that "participants' age, sex, social support, socioeconomic status and past medical history were described and compared between groups to test randomisation". Shouldn't this comparison be at the cluster level? Since this is a feasibility study, the statistical analysis should focus more on descriptive summaries at the cluster and patient levels than any tests that could be underpowered. Reason for age adjustment was not given, and intracluster correlation coefficient (ICC) was not estimated which is an important information for sample size calculation in cluster randomised trials.

In this feasibility study, we have examined the standard analysis that would be undertaken for a full-scale cluster RCT with these outcomes. Although we agree with the importance of considering cluster differences, with only four clusters, we were unable to contribute precise estimates of the intra-class correlation or other measures of inter-cluster variation. Instead, we focus on interpreting any large differences observed in the section “Sample size calculation for a definitive study”. Age adjustment was undertaken because of a difference between groups, described in Table 2.

RESULTS: Confidence intervals are not required for recruitment rates.
We have removed the confidence intervals on pages 15 and 16.
Minor typos are to be checked and corrected .

We have corrected the typographical errors on pages 15 and 16.

The flow diagram should follow suggested format for cluster randomised trials, please refer to "Consort 2010 statement: extension to cluster randomised trials".

We apologise for this and have revised the study flow diagram (Figure 1).

Baseline characteristics need to be reported at both cluster and individual participant levels.

We feel that a list of individual participants’ baseline values would be unnecessary for most readers, and would present a threat to the anonymity of the data. We have however added a new table, giving a further break down of statistics.

With the nature of the feasbility study aiming for collecting necessary data for a definitive trial, descriptive statistics are more informative than statistical tests. For clinical outcomes both means and standard deviations should be reported at scheduled visits by treatment groups, and if important, change from baseline to 6 and 12 weeks.

Thank you; we have added information within a new table.Intracluster correlation coeffcients for important outcomes need to be estimated.

With only four clusters in the feasbility study, assuming ICC=0 in sample size calculation for a definitive trial is not justified.

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We agree that more information is needed for future studies and have added an alternative sample size calculation.

Cost-effective analysis may require review from an economist.

Our cost data has been prepared and the manuscript reviewed by our health economist (Professor Gage)

The CONSORT checklist needs to follow the extension for cluster designs, as stated in the footnote.

We apologise for this oversight and have completed and enclosed the CONSORT checklist with extension for cluster randomised trials.

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