

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)	Resource use of health care services one year after stroke: a secondary analysis of a cluster-randomized controlled trial of a client-centred activities of daily living intervention
AUTHORS	Tistad, Malin; Flink, Maria; Ytterberg, Charlotte; Eriksson, Gunilla; Guidetti, Susanne; Tham, Kerstin; von Koch, Lena

VERSION 1 – REVIEW

REVIEWER	Dr Tash Brusco La Trobe University; Monash University; Cabrini Health
REVIEW RETURNED	02-Mar-2018

GENERAL COMMENTS	<p>Resource use of health care services one year after stroke: subgroup analysis of a cluster-randomized controlled trial of a client-centred ADL intervention</p> <p>General comments</p> <p>I thank the authors for undertaking this work. It is interesting and relevant. Throughout the manuscript I continued to ask myself the question “what have they chosen not to complete an economic analysis?” With all the health service utilisation data you have collected, there would be a great story to tell on the cost (or cost effectiveness / cost utility given you collected life satisfaction and impact of stroke at baseline and at 12/12) of the intervention. Adding this additional layer to the health service utilisation, may have greater impact on policy makers and decision makers who are bound by financial limitations.</p> <p>Minor revisions</p> <p>1) Abstract</p> <ol style="list-style-type: none">a. Consider adding a “background” section that notes “the provision of CADL has reported better patient outcomes, although the cost (or associated health service utilisation) of including CADL in the first year post stroke is unknown”.b. In the abstract you note that you collected life satisfaction and impact of stroke at baseline and at 12/12 but you don’t present these results in the
-------------------------	--

	<p>abstract.</p> <p>c. Conclusion – can be more definite, remove the word “appear” (and remove this throughout the discussion section and final conclusion as well).</p> <p>2) Introduction</p> <p>a. P6 L16 change the word voices to concerns</p> <p>b. P6 L34 change “above the age of 65” to “aged 65 and above” – I assume inclusion is at 65 not 66 (as that is the usual)</p> <p>c. P6 L53 be consistent, here you state “usual ADL intervention” in the abstract you state “ADL intervention as usual”</p> <p>d. P6 L54 the word agency does not make sense</p> <p>e. P7 L6 this last sentence is hard to follow. “social-demographics and capacity in ADL”. Can you please reword this with the same terminology from the methods.</p> <p>3) Methods</p> <p>a. P8 L19 It is noted that only participants from the Stockholm County met the criteria. This is a result, not the methods. Please remove from all places in the methods and place in the results section.</p> <p>b. Please review your terminology and be 100% consistent. For example, P9 you refer to “ADL before stroke and further at 12 months” and then in the following paragraph refer to “ADL at baseline and as 12 months”.</p> <p>c. P10 Statistical Methods, “Socio-demographics and aspects of disability” are vague / inconsistent terms and need to be defined in consistent terminology with the rest of the paper</p> <p>4) Results</p> <p>a. P11 Characteristics of the participants – you are presenting the 12 month results in the characteristics section. Usually this is the demographics and possibly some of the baseline measures that define the characteristics of the participants (not the results at 12 months)</p> <p>b. P16 L21 – please replaced the words “summed up”, maybe totalled.</p> <p>5) Discussion</p> <p>a. This can be a little stronger in your first paragraph and the conclusion. The results found no increase in health service utilisation in the first year post stroke with the inclusion of the CADL model of care into the post stroke management. In fact, there were some areas of health service utilisation, inpatient care, where there was a significant reduction in utilisation without a cost shift into the community post discharge from the health service.</p> <p>b. P30 L8 Sentence starting with Moreover,.... I could not understand this sentence.</p> <p>c. P31 L12 Consider adding to the last sentecen of the conclusion “..... through a full powered RCT with an economic evaluation” (noting that this sub-group analysis was not full powered)</p>
--	---

	<p>6) Tables</p> <ol style="list-style-type: none"> a. Table 1 and 2 – SIS in one section (L40) then full words if Stroke Impact Scale in another section (L50). Be consistent. b. Table 1 – given the BI was sig diff at baseline, shouldn't you report the change score, not just the final score at discharge. The UADL was significantly less dependent at baseline. <p>Major revisions</p> <ol style="list-style-type: none"> 1) Abstract <ol style="list-style-type: none"> a. Nil 2) Introduction <ol style="list-style-type: none"> a. Nil 3) Methods <ol style="list-style-type: none"> a. Nil 4) Results <ol style="list-style-type: none"> a. Nil 5) Discussion <ol style="list-style-type: none"> a. Nil
--	--

REVIEWER	Sara Berkeley UNC-CH, USA
REVIEW RETURNED	16-Mar-2018

GENERAL COMMENTS	<p>This topic is one of great interest and the authors have been thoughtful about quantifying healthcare utilization after stroke. The primary associations of interest are somewhat lost in a plethora of tables and results. Please be more concise throughout. Below I have included specific ideas for improving the methods and results of this paper.</p> <p>This study is referred to as a 'subgroup' analysis. Please clarify the subgroup of interest. It seems to be instead a secondary analysis based on availability of administrative data. That isn't a 'subgroup' of interest.</p> <p>Explain more the a priori reason the analysis was stratified by geriatric versus home rehabilitation. The sample size is quite small and unless there is heterogeneity of effects, power will be higher with a combined analysis. There is no reason to stratify if effect of CADL on outcomes of interest are similar in the 2 groups. This will also make interpretation of results easier for the reader by reducing the amount of information presented in the tables. One could test for an interaction between the exposure of interest and type of rehab and include this information in the results.</p> <p>In the methods, clarify how many of the 16 trial centers were included in this analysis Clarify the outcomes of interest. The 'Statistical Methods' section suggests there are 4 outcomes (second paragraph). However, a plethora of items is listed in the section 'Outcomes'</p> <p>Explain the statistical analysis methods more clearly. What types of models were used, e.g. logistic, linear; were multi-level models used to account for patient clustering within units? What effect estimates are being presented in the tables? 'Beta' is not an appropriate label</p>
-------------------------	--

	<p>for the estimate of interest. Please interpret this for the reader.</p> <p>Tables: There are too many tables and too much data presented in this paper. Please focus the presentation of the results. The tables that show associations of the exposure of interest (CADL vs. usual care) on outcomes should not include intercept estimates or covariates. The reader simply needs to see the effect estimates of interest with 95% confidence intervals. Tables 5a-6b can be combined into far fewer tables and the results need to be presented more clearly. Suggest ordering the tables so that the point estimate and 95% CI are next to each other and p-value is in the last column.</p>
--	---

VERSION 1 – AUTHOR RESPONSE

Reviewer	Comment	Authors' response	page
Editor	Please include the location and expand "ADL" in the title.	This has now been amended.	1
Editor	Please complete and include a STROBE check-list, ensuring that all points are included and state the page numbers where each item can be found.	We have completed and included a STROBE checklist.	
1	This study is referred to as a 'subgroup' analysis. Please clarify the subgroup of interest. It seems to be instead a secondary analysis based on availability of administrative data. That isn't a 'subgroup' of interest.	Thank you for your suggestion, this has now been amended	1,3,7,8
1	Explain more the a priori reason the analysis was stratified by geriatric versus home rehabilitation. The sample size is quite small and unless there is heterogeneity of effects, power will be higher with a combined analysis. There is no reason to stratify if effect of CADL on outcomes of interest are similar in the 2 groups. This will also make interpretation of results easier for the reader by reducing the amount of information presented in the tables. One could test for an interaction between the exposure of interest and type of rehab and include this information in the results.	Thank you for your suggestion. Previous research has shown that there is a difference in outcome in rehabilitation when provided at home compared to when provided at hospital (Fearon et al. 2012, The Cochrane database of systematic reviews) and the intention already when the study was planned was to perform analyses separate for the different stratas. Further, recently conducted analyses shows a difference in outcome of C-ADL between the geriatric and home rehabilitation groups (in manuscript) and we have therefore chosen to keep the stratified analysis. We have also consulted our statistician in this issue and she advised us to keep the present stratification.	
1	In the methods, clarify how many of the 16 trial centers were	This has now been added to the result section of the manuscript in line with	10

	included in this analysis	advice from reviewer 2.	
1	Clarify the outcomes of interest. The 'Statistical Methods' section suggests there are 4 outcomes (second paragraph). However, a plethora of items is listed in the section 'Outcomes'	Thank you for your suggestion. We understand that this might make the manuscript confusing and we have therefore chosen to remove the 12-months data from the manuscript and clarified that the data on assistance in ADL and capacity in ADL is "clinical characteristics".	8
1	Explain the statistical analysis methods more clearly. What types of models were used, e.g. logistic, linear; were multi-level models used to account for patient clustering within units? What effect estimates are being presented in the tables? 'Beta' is not an appropriate label for the estimate of interest. Please interpret this for the reader.	<p>We have now clarified that the analyses are multiple linear regression analyses. We have not accounted for patient clustering but analysed the groups as independent.</p> <p>These considerations and decisions are made in collaboration with our statistician.</p> <p>We have also clarified that we present the regression coefficient in the tables.</p>	9
1	Tables: There are too many tables and too much data presented in this paper. Please focus the presentation of the results. The tables that show associations of the exposure of interest (CADL vs. usual care) on outcomes should not include intercept estimates or covariates. The reader simply needs to see the effect estimates of interest with 95% confidence intervals. Tables 5a-6b can be combined into far fewer tables and the results need to be presented more clearly. Suggest ordering the tables so that the point estimate and 95% CI are next to each other and p-value is in the last column.	<p>As stated previously, we have taken away the 12-months data as we realize that this might be confusing. We have chosen to keep the detailed tables on use of health care services during the first year after stroke as we believe that these tables provide interesting information and increases the transparency in subsequent multiple linear regression analyses.</p> <p>As we want to illuminate also the impact of the factors that were included in the analyses as co-variate and present this to the audience, we have chosen not to remove these from the tables. Further, we do not believe that it would be possible to combine the tables 5a-6b into fewer tables as the dependent variable and/or the strata differs between the tables. These considerations and decisions were made in collaboration with our statistician.</p> <p>We have changed the ordering of the tables according to your advise.</p>	

2 Abstract	Consider adding a “background” section that notes “the provision of CADL has reported better patient outcomes, although the cost (or associated health service utilisation) of including CADL in the first year post stroke is unknown”.	This has now been clarified in the background. <i>The CADL intervention has previously been described in detail¹⁵ and no differences were found in patient outcomes between CADL and UADL^{15 16} except a difference in caregiver burden in favour of the CADL¹⁷.</i>	6-7
2 Abstract	In the abstract you note that you collected life satisfaction and impact of stroke at baseline and at 12/12 but you don’t present these results in the abstract.	We agree with comments from reviewer 1 (see above) that there might be too much data presented in the manuscript. We have therefore chosen to remove the 12-months data from the manuscript, as these are not outcomes/results in the present study. We have kept the baseline data on functioning to inform the reader about the baseline characteristics of the participants.	
2 Abstract	Conclusion – can be more definite, remove the word “appear” (and remove this throughout the discussion section and final conclusion as well).	The sample in the study was quite small, and the ability to identify differences might be limited. Therefore, we consider that we are not able to draw robust conclusions and prefer to keep the word “appear” .	
2 Introduction	P6 L16 change the word voices to concerns	This has been amended.	6
2 Introduction	b. P6 L34 change “above the age of 65” to “aged 65 and above” – I assume inclusion is at 65 not 66 (as that is the usual)	This has been amended.	6
2 Introduction	P6 L53 be consistent, here you state “usual ADL intervention” in the abstract you	This has been rephrased in the abstract.	6

	state “ADL intervention as usual”		
2 Introduction	P6 L54 the word agency does not make sense	This has been reworded and the new wording reads as follows: <i>The aim of the CADL intervention was decrease dependence on assistance in daily activities and restriction in participation in everyday life</i>	6
2 Introduction	P7 L6 this last sentence is hard to follow. “social-demographics and capacity in ADL”. Can you please reword this with the same terminology from the methods.	This has been amended to “sociodemographics and clinical characteristics”	7
2 Methods	P8 L19 It is noted that only participants from the Stockholm County met the criteria. This is a result, not the methods. Please remove from all places in the methods and place in the results section.	This information has been moved to the result section.	
2 Methods	Please review your terminology and be 100% consistent. For example, P9 you refer to “ADL before stroke and further at 12 months” and then in the following paragraph refer to “ADL at baseline and as 12 months”.	This is correct; the assessment tools were used for different time points. The Katz Extended ADL Index was used to capture data on dependence/independence in ADL before stroke whereas the Barthel Index was used to assess capacity in ADL at baseline. This has also been clarified in the method section and in the captions in Table 1 and 2.	9, 12, 13
2 Methods	P10 Statistical Methods, “Socio-demographics and aspects of disability” are vague / inconsistent terms and need to be defined in consistent terminology with the rest of the paper	This has been amended to “socio-demographics and clinical characteristics”. We also believe that the decision to remove the 12-month data made this clearer.	9

2 Results	<p>P11 Characteristics of the participants – you are presenting the 12 month results in the characteristics section. Usually this is the demographics and possibly some of the baseline measures that define the characteristics of the participants (not the results at 12 months)</p>	<p>We believe that the decision to remove the 12-month data (see above) meet this comment. We agree that we had to make the distinction between the real outcome (resource use) and the description of the sample clearer.</p>	
2 Results	<p>P16 L21 – please replaced the words “summed up”, maybe totalled.</p>	<p>This has been amended.</p>	14
2 Discussion	<p>This can be a little stronger in your first paragraph and the conclusion. The results found no increase in health service utilisation in the first year post stroke with the inclusion of the CADL model of care into the post stroke management. In fact, there were some areas of health service utilisation, inpatient care, where there was a significant reduction in utilisation without a cost shift into the community post discharge from the health service.</p>	<p>The sample in the study were quite small, and the ability to identify differences might limited. Therefore, we consider that we are not able to draw robust conclusions and prefer not to be strong in the conclusion. However, we have changed the first paragraph of the discussion based on your suggestion.</p>	27
2 Discussion	<p>P30 L8 Sentence starting with Moreover,.... I could not understand this sentence</p>	<p>This sentence has been rephrased:</p> <p><i>“Moreover, they experienced that the intervention enabled them to feel as owners of their own rehabilitation process”</i></p>	28
2 Discussion	<p>P31 L12 Consider adding to the last sentecen of the conclusion “..... through a full powered RCT with an economic</p>	<p>Thank you for your suggestion, we have added this to the conclusion.</p>	29

	evaluation” (noting that this sub-group analysis was not full powered)		
2 Tables	Table 1 and 2 – SIS in one section (L40) then full words if Stroke Impact Scale in another section (L50). Be consistent.	We have removed this data from the manuscript.	
2 Tables	Table 1 – given the BI was sig diff at baseline, shouldn’t you report the change score, not just the final score at discharge. The UADL was significantly less dependent at baseline.	As we consider this data as clinical characteristics and not outcome, we have chosen to report only these figures.	