Author's response to reviews

Title: Perceived wellbeing of patients one year post stroke in general practice - Recommendations for quality aftercare

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Author's response to reviews: see over
Dear Sir / Madam,

We again would like to submit the attached revised manuscript, "Perceived wellbeing of patients one year post stroke in general practice - Recommendations for quality aftercare," for reconsideration for possible publication in the BMC Neurology.

We highlighted with red underlines all changes made when revising the manuscript.

In the following text a point-by-point response to the concerns of the reviewers is given.

Reviewer: Jorunn Drageset

1) Abstract - Background: This purpose does not cover the purpose of Article s, I recommend that it is identical.
   We adjusted the section in the background about the purpose of the study.

2) Introduction: Last sentence p 5, which variables are compared to the Dutch population? This is unclear (see table 3).
   The purpose of this study is to examine changes in well-being of patients one year after stroke, who returned to their home immediately after discharge from a hospital and to determine factors that may influence changes in well-being. The health-related quality of life is compared to the health-related quality of life of the general Dutch population of the same age.

3) Study design: I miss inclusion criteria.
   We think this is a misunderstanding, because the inclusion criteria are written in the text: all patients who were admitted to the Department of Neurology, Martini Hospital Groningen, between November 2006 and October 2007, after having an ischemic stroke. This were 244 patients (see text article – we changed this part to make it more clear).
4) Regarding the exclusion criteria, text and Figure 1 shows differently. Rehabilitation centre, and other hospital department, was it included or excluded? This was unclear. I recommend this to be clearer.

We excluded all patients who went to a nursing home, rehabilitation centre and other hospital department. We changed this in the text and we changed Figure 1. Flow chart of selection of patients.

5) First paragraph, penultimate sentence, p 6. Please write the ethical code.

We don’t fully understand what you mean by ethical code. The MEC (medical ethical committees) of the Martini Hospital has agreed this study (17-01-2008). Also see the attachment with the article.

6) First paragraph, last sentence p 6 regarding informed consent? What about patients with mild dementia?

There was no official diagnosis of dementia, but when these patients were in hospital for stroke, the neurologist found some clues for possible mild cognitive disorder in the anamnesis. In our opinion we had to mention it as a patient characteristic. But this had no consequences for treatment and guidance. Since these patients are functionally independent and do not have an official diagnosis, we considered them capable of understanding the patient information and giving informed consent. See also point 7.

7) Regarding dementia – see table 1-. Regarding the questionnaire SF-36 and HADS, this questionnaires are not intended to use with patients with diagnose of dementia. Did you have anything form that excluded patients with a diagnosis of dementia?

See also point 6. We didn’t exclude these patients because there was no official diagnosis dementia. The patients are functioning independently and knew what happened in the former year and how they function now and a year ago. As back up, we have interviewed these three patients concomitantly with their partner. So we have build in a check if patients were understanding the questions and if they were answering right. We changes the term ‘dementia’ in table 1 into mild cognitive disorder.

8) Patients were interviewed face to face with standardized questionnaires, Got the interviewer some training?

Yes, the interviewer is a medical practitioner and had enough training to do a interview or anamnesis and followed training with a neurologist to take the questionnaires.

9) Last sentence p 7; smoking, reading, use of alcohol is probably not physical exercise? I recommend that to be made clearer

We changed this part and hope it is more clear now.
10) Statistical analyses
How are the variables controlled for confounders?
The sentence regarding Bonferroni test must be made clearer
Since several of these independent variables might probably be correlated, why
not performed multivariate regression analysis to estimate the effect of each
independent variable adjusted for the others variables? The Independent
variables that were significant in the ANOVA could be included in the multiple
linear regression analysis.

*In principle we agree with the reviewer that a multiple regression analysis would*
*estimate the effect of each independent variable controlled for all other variables.*
*However a rule of thumb states that for each independent variable in a regression model*
*there should be at least 10 observations. Another rule states that it is preferable set the p-
*value for inclusion of independent variables somewhat higher than 0.05, say 0.20. In our*
case that would mean that at least six independent variables are candidates for inclusion
*in a multiple regression model. However there are only 57 observations available which*
*means, that a multiple regression analysis would result in very unstable estimates. This is*
*why we did not perform such an analysis. In the univariate analysis we explored the*
effect of nine independent variables. We agree with the reviewer that those variables are
probably not independent of each other. This means that to maintain an overall
“protection level” of 5% a correction for multiple testing would be in order. However we
decided not to perform such a correction since the p-values are merely interpreted as an
indication of the strength of the relationship between the independent variables and the
score on the Barthel Index. So we wrote in the article: ” Despite the relatively large
number of statistical tests that were done, we decided not to correct for ‘multiple testing’
(for instance by means of the Bonferroni method). Instead, the p-values are merely given
as an indication of the strength of the evidence”.

11) Results: Enter the response rate.
*We changed it. See article.*

12) Functioning: “Home for elderly”, this was not clear in the exclusion and inclusion
criteria. What kind of care received the patients? Could it be that Home for elderly has
less physical limitations in the environments than the patients home? If this is right it will
probably influence the score on Barthel index

*We made it more clear in the inclusion criteria. We mean by an old-people’s home, a*
*retirement home and changed this in the text of the article. In a retirement home people*
can get extra care when necessary; like food, taking care of medication or when there’s a
medical problem. These patients were living there already before stroke and have no
extra care. Reasonably there’s less physical limitations in the environment of an old-
people’s home. We show that people living in an old-people’s home have a lower Barthel*
than people living in a house for themselves. But this doesn’t influence the score on the
Barthel, because this is an objective questionnaire that checks if people can still do
certain things like walking the stairs or go to the toilet themselves. This has nothing to do
with the actual situation in their environment and if they have to do certain things.

13) Daily occupations: Many men were married in the study; it is likely that the
women spouses take housekeeping? I recommend that this to be discussed.
*We actually have written this in the results, but now put it down in the discussion.*
14) Health-related quality of life; Is it only sf-36 to be compared, if the case is unclear until the method capitals. Other sections, use the subdimensions
   We don’t fully understand what you mean by this. This section is only about the SF-36. I changed it in the capital. In the text we use the subdimensions of the SF-36 (or the so called health scales).

15) Discussion; Other sections, it is comparable with the study conducted in Taiwan?
   Yes it is a comparable study. They also interviewed stroke patients one year after discharge from hospital who went back to the community and used the SF-36. Age is the same for both groups of patients. Their group of patients was 65-88 years old and our group is 65-91.

16) Third paragraph p. 14, The sentence that started with “These stroke patient, type in this study…. Put in the text “in the present study”
   We changed this section.

17) Conclusion; Make your conclusion shorter. Include only the main findings. It is not necessary two write the last sentence. I would recommend that you do not emphasize the text of the article.
   We made the conclusion shorter and we removed the last sentence of the conclusion.

Reviewer: Timothy Kwok

1) It was not a prospective cohort study. Apart from Barthel index, none of the measurements done at year one was measured on hospital discharge. It was a cross sectional study performed at year one after stroke. Authors should not claim that they have measured changes in anything except Barthel index.
   We changed the term prospective cohort study. We also removed in the title and text that we measured changes in things.

2) The associations between Barthel index and social circumstances and mood are not the subject of this study and the findings are not novel. Suggest deleting table 2 and the presentation and discussion on these associations.
   We think this is relevant to the subject of the study. We would like to know something about well-being of stroke patients one year after stroke. Barthel index is relevant in this and we think that things that influence this are relevant too. In the discussion we compare this with other studies, but studies about social circumstances and Barthel in the Dutch population we couldn’t find.

3) The functional status as described by categories of Barthel index should be included in table 1.
   We also included the Barthel index in table 1.

4) There was one subject who had missing data. This should be mentioned in results.
   We’ve checked the table’s and changed table 1. In table 2 and 4 there are missing data too. We have mentioned it now in the first paragraph of the results. In table 2 one person is missing because the patient did not know what to answer in the questionnaire about daily occupations. To avoid guessing and wrong answers, we excluded the patient for this
In the questionnaire HADS 2 persons didn’t know how to answer, so we’ve no data about them. This results in 2 missing persons in table 4.

5) In discussion, some information has been added on what community interventions may be tried to improve health related QOL in stroke patients. More elaborations will be welcomed.

Unfortunately we do not have more elaborations about community interventions.

Reviewer: Ashma Krishan

Major Compulsory Revisions

1. In the statistical analysis section in the second paragraph, it is not very clear why correction for ‘multiple testing’ is not carried out. Also p-values are not “an indication of the magnitude of the difference that was found.” Instead ‘p-values are an indication of the strength of the evidence’. Hence, a p-value of 0.001 is highly significant and shows that there is strong evidence, a p-value of 0.055 is borderline significant and shows that there is moderate evidence and a p-value of 0.45 is not statistically significant and shows that the evidence is rather weak. Thus, it seems that the interpretation of the p-values needs to be adjusted in many cases.

We are grateful for the correction of the reviewer for our formulation. Indeed the p-values are only provided as an “indication of the strength of the evidence” and this is precisely the reason we did not perform any correction for multiple testing. We changed the text accordingly. Furthermore we would like to refer the reviewer to the answer we gave to a similar remark of the first reviewer (point 10).

2. It seems there is a significant amount of missing data in Table 1, such as only reports number of patients living alone, in the type of stroke category it only adds up to 93%, and for brain hemisphere it again only adds up to 91%. It would help if the missing data was reported and categorised in some way.

Yes, we understand. We’ve added these missing data in table 1.

3. It seems for Table 2 non-parametric methods have been used. It is very unclear why the mean barthel index value is reported then. In the first instance the normality assumption should be mentioned in the methods section and if the assumption is not valid then the median and range should be reported rather than the mean value.

We used non-parametric methods with the Barthel, because there was no normal distribution, so the conditions of the paired T-test were not met. In table one the Barthel (median and range) is added after advice of the second reviewer. We added the following in the methods section: Since the number of observations is rather low deviations of normality of the Barthel Index could not be assessed in a proper way. Therefore we used non-parametric tests. (Wicoxon ranksum test for correlated observations and Mann-Whitney/Kruskall-Wallis tests for independent observations)

4. For Tables 3 and 5 it is unclear what ‘Change in Health’ is and where is comes from. There is no mention of it in the methods chapter. This needs to be either defined and mentioned in the methods chapter or removed from the analysis.

We accidentally forgot to explain what we mean by this. To avoid confusion, we removed this section.
5. In the results chapter in the section on ‘Mood disorder’ in the last paragraph, it says that correlations could not be found for the given variables. However, it is not very clear what is meant by could not be found—were the correlation values equal to zero or were they very close to zero. We understand. The p-values in this section varied from 0.245 to 0.680. So no relation between anxiety disorder or depression and social status (living alone or with a partner) or caregiver strain (burden or no burden) could be found. We changed this section and added the range of p-values.

Minor Essential Revisions

1. In the statistical analysis section in the first paragraph, it says that one of the methods used is a t-test. It should be made much clearer whether it was a one-sample t-test or a 2-sample t-test. We made this more clear in the statistical section and in table 4; Comparison of SF-36 subscales with population based values was done with Student's t-test for independent observations.

2. In the results chapter in the section on ‘Functioning’ in the first paragraph, it says “There is no difference between men and women.” This sentence should be re-phrased and correctly written as either ‘There is no significant difference between men and women’ or ‘There is no evidence of a significant difference between men and women’, whichever is preferred. This should be the case for all of the interpretations. We changed it in all the results.

3. In the results chapter in the section on ‘Functioning’ in the second paragraph, the p-value for housekeeping is written as p=0.000 however, it should be changed to p<0.001. This should be the case for all p-values written as p=0.000. We changed it in all the results.

4. In the results chapter in the section on ‘Daily occupations’ in the third paragraph, it says “A lot of patients have trouble keeping their hobbies.” However, from Table 2 it seems that about 62% do as much as before their stroke. There seems to be a huge disagreement between the two results. We changed this section and wrote down only percentages now.

5. The title for Table 4 seems to be slightly misleading. Slight unsure as to what is meant by “statistical significant results of the independent-samples T-test or one-way ANOVA”. A t-test is not carried out for the results in that table. Also, Table 4 reports non-significant and significant results. Yes indeed, we removed that part of the title and changed table 4.

Minor issues not for publication

1. In the abstract in the results section, it says “ADL independency is correlating to a better quality of life.” It may be a better idea to say ‘ADL independency is correlated with a better quality of life.’
Thank you, we changed it.

2. In the statistical analysis section in the first paragraph, it seems the last sentence should read ‘…on the BI and HRQOL we used…’.
   
   We tried to make the sentence more clear and fluent.

3. In the results chapter in the second paragraph, it may be a better idea to say ‘The detailed baseline characteristics…’.
   
   Yes indeed, we adjusted this part.

4. In the results chapter in the section on ‘Caregiver Strain’ in the third paragraph, it says ‘…between age, functioning or HRQOL of stroke…’. It seems the sentence should read ‘…between age, functioning and HRQOL of stroke…’.
   
   We changed this.

5. In the results chapter in the section on ‘Caregiver Strain’ in the third paragraph, it says ‘There is a moderate correlation for caregiver…’. The sentence should read ‘There is a moderate and negative correlation for…’.
   
   Yes indeed, we adjusted it.

Level of interest: An article of importance in its field.

Quality of written English: Needs some language corrections before being published.

After adjusting all concerns of the reviewers in the article, we have sent the article to a language centre to do language corrections.

All authors have read and agreed to the content of the manuscript. The research that is reported in the manuscript has been performed with the approval of an ethics committee. 'All authors declare that they have no competing interests'.

This article has not been published or accepted for publication. It is not under consideration at another journal. No other papers using the same data set have been published.

I am looking forward to your reply.

Yours faithfully,

Ms L. de Weerd

Also on behalf of,

A.W.F. Rutgers, K.H. Groenier and K. van der Meer