Author's response to reviews

Title: Natural course of care dependency in residents of long-term care facilities: Prospective follow-up study

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Author's response to reviews: see over
Leiden, January 21th, 2014

Dear (deputy) editors of BMC Geriatrics,

Herewith we would like to re-submit our revised manuscript “Natural course of care dependency in residents of long-term care facilities: Prospective follow-up study”, for review to BMC Geriatrics.

We thank the referees for their well-considered comments and the opportunity to re-submit a revised version of our manuscript.

In this document we reply to the comments of the referees on the manuscript. The changes that were made according to the referees’ comments were highlighted in the revised manuscript.

We hope you will consider our manuscript for publication in BMC Geriatrics.

On behalf of all authors,

Yours sincerely,

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Reviewer: Karin Wolf-Ostermann

**Major comments:**

**Background:**

Q1. Please give some information what is known in literature about care dependency and its relation to personal or institutional characteristics since this background information is completely missing.

A1. We have moved a paragraph from the discussion section to the introduction to describe the relation between patient characteristics and ADL performance and care dependency. Although we agree that institutional characteristics could influence care dependency, we didn’t include this because this was out of scope of this study. Besides, we did not find any scientific literature about the relationship between institutional characteristics and care dependency.

This paragraph reads now: “Previous studies have shown that i.e. nutritional status, cognitive impairment, absence of daily contact with proxies, depression, neuropsychological deficits, incontinence and infections were mentioned as predictors for deterioration in ADL performance of vulnerable older people. Deterioration in ADL will lead to more individual care demands and higher care dependency.”

**Methods:**

Q2. Please describe how the nursing homes were chosen to participate in the study, how did you recruit residents in these nursing homes (was is some type of cluster-randomisation?, did you estimate the number of persons needed? ...)

A2. This study was nested in the CRANBERRY trial, a double-blind randomized placebo-controlled multi-center trial. Twenty-one LTCF organizations from the University Nursing Home Research Network (UVN-ZH) in South-Holland, the Netherlands, participated. To participate in the network, there were no selection criteria concerning characteristics of the LTCF organizations.

For a full description of the recruitment of the study participants and loss-to follow-up we refer to the CRANBERRY trial just published in the January 2014 issue of JAGS (JAGS 2014;62:103-110: DOI: 10.1111/jgs.12593). I will send the paper with this manuscript for additional information.

Q3. Another question that occurs to me: why did you not include nutrition as a factor of interest concerning care dependency?

A3. The present study was nested in the CRANBERRY trial. This gives us the possibility to explore whether there are predictive factors of change in care dependency (measured with the Care Dependency Scale). Since nutrition data were out of the scope of the data collection for CRANBERRY, we do not have information on the nutritional status of our residents.

**Statistical analysis:**

Q4. Why didn’t you model the linear mixed models (LMM) as multilevel analyses since there might be an influence of the nursing homes on the higher level which might not be modelled adequately otherwise. Why didn’t you include (on the first level) personal characteristics like age, functional and cognitive status, comorbidity etc. in the modelling?
A4. We didn’t do a multilevel analysis since we were interested to explore personal characteristics on the course of care dependency. As earlier explained, we did not include factors dependent on care organization.

Q5. Why did you look only at 6-months periods when you have a longitudinal design of 12 months?

A5. We looked at two 6-months periods since we wanted no bias through the high mortality, and we do not want to assume that the model is linear (the first 6 months could be different in slope compared to the second period of 6 months).

Q6. Are the stated p-values nominal ones or did you correct for multiple testing?

A6. The p-values are nominal ones, we didn’t correct for multiple testing within the prediction model.

Results:
Q7. Please describe the loss-to follow-up in numbers and characteristics. Is there a statistical difference to be seen concerning "survivors"?

A7. The dropout in the study was through mortality or missing CDS scores at 6 or 12 months of follow-up. In table A below you will found the comparisons of resident’s characteristics and dropout.

We added this information to the results section of the paper, it now reads: “At 6 months follow-up, 132 participants (14.8%) had died and in 44 participants (4.9%) the CDS scores were missing, resulting in 714 participants (80.2%) at 6 months. At 12 months follow-up, another 129 participants (18.1%) died and in 21 participants (2.9%) the CDS scores were missing, resulting in 564 participants with complete measurements (79.0%) at 12 months.”
Table A. Comparison of resident characteristics at baseline, between participants, the deceased and participants with no CDS score at 6 and 12 months of follow-up

<table>
<thead>
<tr>
<th></th>
<th>6 months follow-up</th>
<th>12 months follow-up</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Participants (n=714)</td>
<td>Deceased (n=132)</td>
<td>No CDS score at 6 months (n=44)</td>
</tr>
<tr>
<td>Female (%)</td>
<td>552 (77.3)</td>
<td>89 (67.4)</td>
<td>33 (75.0)</td>
</tr>
<tr>
<td>Age in years, median (IQR)</td>
<td>84 (79-88)</td>
<td>86 (81-90)</td>
<td>83 (78-86)</td>
</tr>
<tr>
<td>Length of stay on the ward in months, median (IQR)</td>
<td>20 (6-43)</td>
<td>12 (3-34)</td>
<td>8.5 (4-25.3)</td>
</tr>
<tr>
<td>Baseline CDS score, median (IQR)</td>
<td>44 (31-56)</td>
<td>39 (28-52)</td>
<td>50 (38-62)</td>
</tr>
<tr>
<td>Myocardial infarction (%)</td>
<td>62 (8.7)</td>
<td>16 (12.2)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Stroke (%)</td>
<td>155 (21.8)</td>
<td>33 (25.6)</td>
<td>16 (36.4)</td>
</tr>
<tr>
<td>Cancer (%)</td>
<td>130 (18.4)</td>
<td>24 (18.6)</td>
<td>10 (22.7)</td>
</tr>
<tr>
<td>Diabetes mellitus (%)</td>
<td>137 (19.2)</td>
<td>24 (18.2)</td>
<td>13 (29.5)</td>
</tr>
<tr>
<td>COPD (%)</td>
<td>100 (14.2)</td>
<td>23 (18.7)</td>
<td>6 (13.6)</td>
</tr>
<tr>
<td>Urine incontinence (%)</td>
<td>449 (65.9)</td>
<td>90 (69.2)</td>
<td>24 (54.5)</td>
</tr>
<tr>
<td>Urinary tract infection preceding year (%)</td>
<td>292 (41.0)</td>
<td>70 (53.0)</td>
<td>24 (54.5)</td>
</tr>
<tr>
<td>Dementia (%)</td>
<td>551 (78.0)</td>
<td>99 (75.0)</td>
<td>27 (62.8)</td>
</tr>
</tbody>
</table>

*Chi-square test; **Kruskal-Wallis test
CDS=Care dependency scale; IQR=interquartile range
Q8. It remains unclear if the "third-groups" are newly formed at the beginning and after 6 months. This should be clearly described in the methods section. If groups are newly formed than you only can compare sequentially - any information concerning a longer period of time (12 month) is lost.

A8. Yes, the 'third-groups' are newly formed at baseline and after 6 months. We added this information to the manuscript and have indeed looked sequentially.

Q9. I wonder why you use sex as grouping factor when later analyses show, that sex has no significant influence. Did you analyse if there is a correlation to other influencing factors in your setting?

A9. Since we treated sex as effect modifier in the analysis, we stratified on gender specific 33% groups. Women and men were separately ranked into gender-specific 33% groups according to their baseline CDS score. Thereafter we combined the lowest, middle and highest 33% groups for women and men together, to generate three gender-specific CDS groups.

As described in the first version of this paper, we haven't not found any influence of gender on changes in CDS score within the three CDS groups. Because this analysis is confusing we decided to drop the analysis and results from the manuscript.

We checked for co-linearity between the independent variables and dependent variable (CDS score at 6 months) with the Variance Inflation Factor (VIF) and did not find co-linearity between the dependent variable (CDS-score at 6 months) and the independent variables in both the crude and adjusted model. The Variance Inflation Factors ranges between 1.0 and 1.4. This information is added to the results section of the manuscript.

Q10. Discussion:
The discussion needs rewriting since you often only recap results instead of discussing them. This might also be a consequence of not properly investigating literature in the beginning of your article. I can’t follow your conclusion concerning the study of Bürge et al. totally, the results might show some similar trend but that can't be concluded by the facts you present.

Strengths and limitations:
Again you recap results instead of telling about strengths and limitations of the study and its implications. Please describe what are implications of the sample selection, the instruments used, which collected the data and so on. This sections needs a stronger focus to its essential points.

Conclusion:
Again a recapture of results. There are no conclusions drawn which really concentrate on results and give advice for further practice in nursing homes. What is about clinical relevance of your results?

A10. We have rewritten the discussion section, have added some methodological considerations to the strengths and limitations and have rewritten the conclusion.

Minor Essential Revisions:
Background:
Q11. Please give more information concerning the Swiss study you are citing (length of duration, points of measurements ...)


A11. As recommended, we have added in the discussion some more information concerning the Swiss study. This now reads: “A recent Swiss study among 10,199 nursing home residents (70% women, 74% aged 80 years and above) observed a decrease in activities of daily living (ADL) of 35% and an increase in ADL of almost 14% among residents, within a period of median 6 months (SD 3 months) [12]. They used the Minimum Data Set Activities of Daily Living (MDS-ADL) and looked at ADL performance as primary outcome”.

Q12. Figure 1 & 2: Please add a legend and make clear what the tables below are representing.

A12. We added a legend and have rewritten the titles of the two tables.

Reviewer: Martin Smalbrugge

Reviewer’s report:
The article provides additional evidence on the changes in care dependency in LTCF-residents and on the relationship between care dependency and mortality in this population.

Major Compulsory Revisions

Q1. In the abstract, the background, the result and the discussion sections (and maybe also in the title) more specific attention should be paid to the relationship between care dependency and mortality as this is also an important part of the article (see figure 1 and table 2).

A1. We agree that the relation between care dependency and mortality is an important part of our manuscript. We have now given more attention to mortality, as suggested, throughout the whole manuscript.

Q2. The study-population (in and exclusion criteria) should be more detailed: the JAGS article (ref 13) is not available yet, and for assessing the external validity of the study this is essential as inclusion/exclusion criteria for the cranberry trial may result in a specific subpopulation of the LTCF-residents.

A2. In the CRANBERRY trial LTCF residents aged ≥ 65 years were included. Excluded were coumarin users and residents with a life expectancy shorter than one month. We added this information to the methods section. Also a non-responder analysis in the CRANBERRY trial for given informed consent showed no difference between non-responders and responders in age and gender.

The JAGS paper is available now (JAGS 2014;62:103-110; DOI: 10.1111/jgs.12593) and I will send the paper with this manuscript for additional information.

Minor Essential Revisions

Q3. In the method section information about how care dependency is measured is separated from the information about how it is categorized. This categorization information is provided in the first sentences of the paragraph about Statistical Analysis. I would be prefer to receive this information under Care Dependency and a more extensive motivation for the chosen categorization, as there are more ways to investigate care dependency changes (for example choosing a change of more than half of the standard deviation of the mean as a clinically relevant change)
A3. We replaced the sentences about the categorization of care dependency to the section describing care dependency and added more information about our motivation for the categorization in three gender-specific CDS groups.

The text reads now: “Since women and men differ in their baseline care dependency status and the CDS scores were not normally distributed, women and men were separately ranked into gender-specific 33% groups according to their baseline CDS score. Thereafter, we combined the lowest, middle and highest 33% for women and men together, to generate three gender-specific CDS groups. The ‘low score’ CDS group indicates participants most dependent on care and the ‘high score’ CDS group indicates participants the most independent of care”.

And later on:
“For the analysis of CDS change in the subsequent 7-12 months, participants were newly classified in gender-specific 33% groups at the 6-month CDS assessment”.

Q4. In table 3 the variability in care dependency is shown for two periods (0-6 months; 7-12 months). The number of residents in both periods is the same (564). In my opinion in the first 6 months more residents should and could be included: residents who died in the second period can be included in the first period for this analysis.

A4. Thank you for this suggestion. In table 3 we have included the residents who died in the second period to the analysis of the first 6-month period. We changed the table accordingly. The results did not change materially.

Q5. Table 4: I have some questions about this table/the analyses done for this table:
Q5a. Why is this analysis not carried out for the 12 month period?

A5a. We looked at two 6-months periods since we wanted no bias through the high mortality, and we do not want to assume that the model is linear (the first 6 months could be different in slope compared to the second period of 6 months).

Because there were more residents alive at 6 months follow-up, as in the analysis for table 3, we have done the 6-month model again for all participants living at that time.

Q5b. Based on which criteria were the variables myocardial infarction, stroke, diabetes mellitus, COPD and urinary tract infection preceding year excluded from the adjusted model (P value not significant in the crude model? If yes, why then include the first three variables in the adjusted model?)

A5b. The variables myocardial infarction, stroke, diabetes mellitus, COPD and urinary tract infection preceding year were excluded from the model, because they were not significant in the crude model. We added to the methods section that except gender and age all other variables with a p-value \( \leq 0.05 \) were excluded from the adjusted models.

Q5c. Was co-linearity between independent variables like dementia, urine incontinence and baseline CDS score investigated?

A5c. Yes, we investigated co-linearity, but did not find any co-linearity between these independent variables and the dependent CDS-score at 6 months.
We added this finding to the results section in the manuscript. It reads now “We did not find colinearity between the dependent variable (CDS-score at 6 months) and the independent variables in both the crude and adjusted model. The Variance Inflation Factors ranges between 1.0 and 1.4”.

Q6. In the conclusions the relationship between care dependency and mortality could be mentioned as an important finding of this study.

A6. We added the sentence “Highly care dependent residents had an increased mortality risk” to the conclusion in the abstract and main text.

Discretionary Revisions
Q7. In the discussion it is stated: ‘Despite the selected single center study of Dijkstra et al., they found that the degree of care dependency at entry to the study was one of the strongest predictors of follow-up CDS ratings [12].’ Maybe the English is not correct in this sentence. I suppose that the authors state here that ‘in this selected single center study the degree of care dependency at entry to the study was one of the strongest predictors of follow-up CDS ratings’?

A7. Thank you for your reading well. We changed the sentence accordingly and it reads now: “In the selected single center study of Dijkstra et al., the degree of care dependency at entry to the study was one of the strongest predictors of follow-up CDS ratings”.

Q8. The strength and limitations is somewhat lengthy now and includes some information that could be removed:
Q8a. the information about the intramural care settings (‘intramural care settings in which care for the most vulnerable older persons is provided by a multidisciplinary team including elderly-care physicians, nursing assistants, licensed practical nurses, registered nurses and paramedical professionals.’): this information could be provided in the methods sections.

A8a. Thank you for this suggestion, we moved this information to the methods section.

Q8b. the sentence ‘On the other hand, they are not automatically generalizable to vulnerable older persons living at home or in residential homes; in these latter populations we expect differences in care dependency status, comorbidity and functioning in ADL.’ Can be removed maybe, as it is no real strength or limitation.

A8b. As suggested, we removed this sentence from the manuscript.