Author's response to reviews

Title: How are falls and fear of falling associated with objectively measured physical activity in a cohort of community-dwelling older men?

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Version: 3
Date: 21 August 2014

Author's response to reviews: see over
Reviewer's report
Title: How are falls and fear of falling associated with objectively measured physical activity in a cohort of community-dwelling older men?
Version: 2 Date: 4 July 2014
Reviewer: Geeske Peeters

Reviewer's report:

General comments

This paper describes the associations between the exposures fall history and fear of falling and the outcome physical activity. Physical activity was measured with accelerometers and four different definitions of physical activity were used. Although the association between falls and fear of falling with physical activity has been studied before, to my knowledge, this is the first study to examine these associations with an objective measure of physical activity in a relatively large sample of community-dwelling older men.

The paper is generally well written, however, the statistical analyses require further clarification. Some decisions in the analytical process are unusual, but there is currently insufficient information to judge whether it is a correct and novel way of approaching these data or incorrect and requiring revision.

We thank the reviewer for their positive comments.

Major compulsory revisions
1. Abstract: I read the abstract first and without having read the rest of the paper, the conclusion seemed to disagree with the results. The last sentence of the results (lines 73-76) seems to suggest that after adjustment for these other variables, the association between falls and FOF and PA are not statistically significant. But it is then concluded (lines 77-78) that falls and FOF are important barriers to gaining health benefits of walking and MVPA. If there are no significant associations, that falls and FOF can’t be barriers. Later, from the text, I understood that these variables are believed to be mediators, but this is not clear from the abstract. If these variables really are mediators (see later comment), it would be helpful to clarify this in the abstract to avoid confusion.

We apologise for the confusion and have added clarification to the abstract to the effect that the associations which were initially statistically significant were attenuated on addition of the potential mediator variables. We also added a sentence to the final paragraph of the introduction to clarify that we aimed to look at what factors may mediate any associations (line 121). The methods section now contains a fuller explanation how mediators were chosen and of the modelling strategy- lines 179-187-

“Mediators between falls history and PA level were chosen if they had been reported to be associated with PA levels and with falls or FOF in other studies, and were also related to falls, FOF and PA levels in our study. These mediators were added one by one, to evaluate the role of each; exercise self-efficacy, exercise outcome expectations (both analysed as standard deviation scores), mobility problems, number of days leaving the house, depression,
health-related quality of life score, and FOF. A final model included all potential mediators to evaluate whether associations between falls and PA were fully mediated.

We have also added text to explain the strategy for selecting mediators (see response to point 7 below). We do think that our main results show that falls and FOF are important barriers to gaining health benefits of walking and MVPA, as model 1 in Tables 2 and 3 shows significant associations—although the subsequent models that look at mediating variables (models 2-9, Tables 2 and 3), seek to investigate pathways through which these associations may occur.

2. Measures (line 138): The definition of sedentary behaviour was based on a cut-point of 100 counts/minute. Results presented in a recent publication showed, however, that a cut-point of 200 is more accurate in identifying sedentary time in older adults (Aguilar et al. ActiGraph GT3X+ cut-points for identifying sedentary behaviour in older adults in free-living environments. J Sci Med Sport 17(3): 293-299).

We have considered this issue carefully and have retained the cutoff of 100 cpm for defining sedentary behaviour, which is the most widely used cutpoint for defining sedentary behaviour among older people[1]. However, in response to the Reviewer’s comment we have examined the effect of using different thresholds (including the cutoffs for uniaxial VT data of 25 cpm recommended by Aguilar[2] and 50 cpm recommended by Clemes)[3] on the key associations reported in the paper. We can confirm that the associations between physical activity and sedentary behaviour with falls and fear of falling are not materially affected by the use of different cutoffs. To take account of this, we have added a brief note on these sensitivity analyses in the Methods (lines 194-196) and Results sections (lines 255-258) and also comment further on the issue in Discussion (strengths and weaknesses, lines 342-348).

3. Measures (line 147/8) and Discussion (lines 257-259): A single item question was used to assess FOF. The text suggests that this question has been validated against FES and SAFE, however, the paper that is referred to here (nr 25) validates the SAFE against the FES and the FOF items developed by Howland. The question used in this paper differs from all three. Has the question been validated? If so, please provide evidence of its validity. If not, please discuss this as a study limitation in the discussion.

We apologise for the confusion- what we intended to convey was that we are using a single item question and that a single item question has been used in other contexts to identify FOF. We were not intending to say that our question had been validated against the measures in the Lachman 1998 paper. For clarity, we have altered the text in the methods (line 148) and added in additional explanation in the discussion section (lines 270-277) where we talk about the measure:

“Our FOF scale is a one item question with 3 possible answers. The scale has construct validity: in line with expectations from other studies,
men with FOF had lower quality of life and more mobility limitations than those who were not fearful[4]. A variety of single item questions have been used in many other studies to identify fear of falls [5]. A similar single item question is reported to correlate well with validated scales including the Falls Efficacy Scale (r=0.43) and the Survey of Activities and Fear of Falling in the elderly scale (r=−0.59)[4].”

4. Measures (line 152)/Statistical methods (line 180): Habitual PA was based on self-reports of participants 10 years earlier. What does this say about “habitual PA” from 10 years ago to now? This measure was used for the sensitivity analyses, but it is unclear what this sensitivity analyses actually tests. Please clarify or remove as it doesn’t seem to add anything to the paper.

We apologise for the confusion. For clarity we have removed this sensitivity analysis.

5. Statistical methods (line 166-168): As log-transformation of MVPA did not alter the results, the non-transformed data were presented. It appears that log-transformation was done to deal with the zero counts in the PA data. However, a log-transformation deals with right-skewed data, not with excess of zeroes. More importantly, rather than examining the distribution of the outcome, it should be examined whether assumptions for linear regression are met (and normal distribution of the outcome is not one of the assumptions!). Please check the assumptions and report whether these were met. If not, adjust your modelling accordingly.

We assure the reviewer that during our analyses we checked assumptions for the models we used; we conducted several tests of normality of the residuals. For the outcomes steps, sedentary and light PA, assumptions for linear regression are met. For MVPA which has an excess of zeros, we tried different transformations (log and square root). We thought carefully about which data to present and we chose to use original units because the log-transformed data doesn’t improve the statistical properties that markedly. Also in the analyses of transformed data, the pattern of results of significant associations and the size of the p values are similar to the untransformed data. (e.g. for model 1, MVPA vs falls, the p-value for “2+ falls vs none” was <0.001 even if we use the log transformed data, while for “1 falls vs none” p-values were 0.941 vs 0.891 for untransformed and transformed data respectively). Therefore, on balance we kept original units because they are very much easier to interpret.

6. Statistical methods (lines 169-175): Although I am unsure whether I interpreted the text correctly, it appears that each day of PA measurement was used as a separate measurement and thus as repeated measurements. In the random effects models, the day of PA measurement was then included as a separate variable to account for the repeated measures. This is an unusual way of analysing these data and I am unsure if this is the correct way to do it. Usually the multiple day measurement of PA is done to account for the day-to-day variation in the data, which is then averaged out by using the mean value as a single outcome for each participant. Could you please explain why this approach was chosen and how it may have influenced the results? Also, did you really do
random effects modelling? Was a random slope or random intercept included? If so, please explain. If not, than the model was in fact a fixed effects model, which is similar to a GEE model (except that it can deal with missing values). What correlation structure was used and did choice of correlation structure affect the results at all?

We did indeed use random effects models with the 3-8 days of measurement nested within the individual. We used a random intercept only option; each serial number has its own intercept, but we estimate a common slope (the adjusted mean value in our tables) for each one of the categories of the exposure variable, (eg falls; 3+ vs. none, and 1-2 vs. none). The correlation structure is set to identity by default because Stata automatically identifies that in a random intercept model the only possible covariance structure is identity. (http://www.stata.com/bookstore/stata12/pdf/xt_xtmixed.pdf).

The benefits of using random effects models for repeated measures data include that we can account for the day of wear effect- ie that men take more steps on the first day than on subsequent days. This effect cannot be accounted for when using a single mean of the weekly data. The random effects models make most use of the available data by estimating the weekly mean and the variation rather than just using a single mean of weekly data which is inefficient as it uses only part of the information available to estimate habitual activity levels. This tutorial paper summarises the benefits of this technique[6].

Our approach using hierarchical models to analyse accelerometer data has been used in many other studies, published in high-ranking epidemiology journals eg in International Journal of Epidemiology and Diabetologia [7,8], generalist journals[9], and specialist physical activity research journals[10-13]. The papers using this methodology span several different physical activity research fields.

We have added more detail to the methods section (lines 174-175) to the methods section to explain that we used stata xtmixed command for the random effects models and that the models had a random intercept and identity correlation structure.

7. Statistical methods (lines 175-180): Please provide a rationale for why each of these variables might be mediators? Simply adding them in and checking whether they attenuate the association is not sufficient to say that a particular variable mediates the association of interest. For a variable to be a mediator, it should be associated with both the exposure and the outcome and a change in the exposure should cause a change in the mediator. This explorative modelling does not seem to answer your research question and could be a secondary research question if examined thoroughly. Also, quality of life was described in the results and tables as a mediator but not listed here.

We apologise for the confusion about the choice of mediators. We agree with the reviewer that for a variable to be a mediator, it should be associated with both the exposure and the outcome and a change in the exposure should cause a change in the mediator. We have added text to the methods section (lines 159-
166 and 179-182) to clarify our procedure for identifying mediators. The mediators were chosen a priori from existing literature, we were interested to understand what might explain the deficit in activity after a fall and among people who are fearful of falling, we therefore examined literature to select the variables that we had data on in our study, that might reasonably be expected to be related to both exposure and the outcome. Once we had done that, we then examined whether each was related to PA outcomes, as well as the FOF and falls exposures in our study, and if so, the variable was retained as a potential mediator and entered into the models.

In the results section, after describing associations between exposure and mediators, ie how falls were related to each of the mediators (lines 205-210), we added a sentence explaining that we also examined associations between and mediator and PA outcomes (line 214-216). We have also added details about the quality of life measure to the list of mediators in the methods section (lines 152-155).

8. Statistical methods (line 181): complete case analyses were done, but random (or fixed) effects modelling should be able to deal with missing values. There do not seem to be many missing values on falls history and FOF, but were there any missing values on any of the confounders or mediators?

We did have missing data on confounders and mediators: for FOF there was a maximum of 1577 participants which reduced to 1398 in complete case analysis (ie n=179, 11% missing) and the equivalent was for falls 1568 reducing to 1398 in complete case (ie n=170, 11% missing). These numbers can be seen in the headings of Table 1, 2 and 3. The hierarchical models help with missing data on the variables which vary over time (in our models, that would be having eg 3 rather than 8 days of the week of PA data), however they do not help recover missing information on the fixed covariates (in our models all the mediators and confounders). We used complete case analyses as the loss to missing data was only around 10% and complete case analysis has the advantage of enabling us to compare models 1-9 over a constant sample of participants rather than over a changing sample.

9. General: I initially thought that, having the four definitions of PA was a strength of this paper. However, looking at the results in Table 2, it seems that the effects of falls and FOF on SB, light PA and MVPA add up to 0, which makes me wonder whether they are actually one measure rather than 3 different measures. It would be good to reflect on this in the discussion.

We have now added a point to the discussion (lines 348-354) to note that the changes in sedentary, light activity and MPVA have to add up to zero. We believe that it is a strength to look at the different intensities of activity, we have independent data on two of the three outcomes (sedentary, light activity and MPVA) and we decided to present all three (plus steps as a fourth outcome which is independent of the other three) as this gives us insights that questionnaire data would not give us.

10. Conclusion (lines 326-328): The wording of the first sentence in the conclusion here and in the abstract seems a bit strange to me: the paper looks at the association between falls and FOF and PA, not at health benefits of PA. Also,
I struggle with conceptualizing falls as a barrier to PA as it I would have thought that it is not the fall itself, but the consequences of the fall that could form a barrier.

We take on board the reviewers point and have clarified that the consequences of a fall may be the barrier to being active- be that injury or over-caution resulting from fear of falling. We made a change to the introduction (lines 92-93) so that the point is clear from the outset.

Minor essential revisions:
11. Abstract (line 68): should “which” be “whom” in this sentence? The text has been amended as suggested.

12. Statistical methods (line 161): Although often applied in research, including a categorical variable as a continuous variable in a linear regression model doesn’t actually say anything about “trends” as the p-value can suggest statistical significant if only one category differs from the lowest. Moreover, a “trend” cannot be shown over 2 categories (FOF). I’d suggest rephrasing as “Linear regression models were used to examine differences in continuous variables ....” The text has been amended as suggested.

13. Results (line 192): It says 3-7 days here and 3-8 days in the statistical methods. The text in the results has been amended to read 3-8 days.

Level of interest: An article of importance in its field
Quality of written English: Acceptable
Statistical review: Yes, and I have assessed the statistics in my report.
Declaration of competing interests:
I declare that I have no competing interests

Reviewer's report
Title: How are falls and fear of falling associated with objectively measured physical activity in a cohort of community-dwelling older men?
Version: 2
Date: 14 July 2014
Reviewer: Nancye May Peel
Reviewer's report:

- Major Compulsory Revisions
  1. Line 205: “Neither PA levels 10 years earlier nor social class were related to falls history.”
Table 1 indicates that the relationship between falls history and manual social class was significant (p=0.002).
Conversely, Line 224 indicates that FOF was related to manual social class even though the p value was non-significant (0.074).
Could the authors please explain why these statements are contrary to the results in Table 1?
We thank the reviewer for picking up these points and have now amended the text in the results to reflect this.
Minor Essential Revisions
1. Line 269: “The deficits in in total volume......”
Delete second “in”
**This change has been made.**

Discretionary Revisions

1. Line 88: “Falls are very common in community-dwelling older adults; approximately one third reporting falling in the past 12 months”
Findings in this study indicate that the fall rate was 20% (line 249), even though the mean age of the cohort was 78 years. The authors further state that this prevalence rate was similar to other studies (line 253). This is debatable since the cited studies (Gill et al, 2008; Tinetti & Williams, 1998; Mendes da Costa et al 2012) found annual falls rates between 30-50%. Zijlstra et al, 2007 and Bruce et al, 2002 quoted fall rates over 6 months and 3 months respectively, making comparison of prevalence rates with the current study more difficult.
The authors should give an explanation as to why their fall rate was low in comparison to the cited studies.

We thank the reviewer for their comment, we have amended the text in the discussion and now say “In our study, prevalence of falls was a little lower than other comparable studies[14–18], and FOF was less prevalent than in some other studies[15,19,20]. This could reflect selection bias, but even if our participants were more active and less fearful of falling than the average, any bias should underestimate true associations between falls or FOF and PA levels. Also, studies which ascertain falls using prospective monthly follow-up may report higher prevalences of falls than studies using a single item recall over the past year”

2. Line 91: “Fallers have lower levels of self-reported PA [7,8].”
The references quoted (Gill et al, 2008; Tinetti & Williams, 1998) examined associations between level of PA and fallers with injury. Gill et al also showed that Injurious falls are associated with lower household but higher recreational PA in community-dwelling older males; the latter finding is contrary to the authors’ statement in Line 91.

We agree with the reviewer’s comment about the paper by Gill et al. We therefore removed this citation.

3. Line 254: “FOF was less prevalent than in some other studies”
This statement is in agreement with cited studies, except that reference 15 (Scheffer et al, 2008) was a systematic review where the reported prevalence of FOF varied between 3 and 85%. Probably this is not an appropriate article to support the authors’ statement in line 254.

We apologise for the confusion, for clarity we have removed the citation of the review in this sentence.

Level of interest: An article of importance in its field
Quality of written English: Acceptable
Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests: I declare that I have no competing interests.

Reference List


