Author's response to reviews

**Title:** Definitions and methods of measuring and reporting on injurious falls in randomised controlled fall prevention trials: a systematic review

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**Author's response to reviews:** see over
To the editor and reviewers:
We appreciate the reviewers’ suggestions for improvement of the manuscript. We have now introduced modifications according to comments made and added a detailed and comprehensive response on every reviewer comment below. Modifications made within the manuscript are marked in red colour.
The manuscript has been correctly formatted according to the BMC journal style. The revisions made to meet the formatting criteria are listed at the end of this manuscript. We hope we have now met with the request made and accomplish the high quality standards of *BMC Medical Research Methodology*.

Sincerely,
Michael Schwenk
Corresponding author

Reviewer 1 (Magnus Karlsson)

1. “Actually I have no comments or suggestion for changes. I think the paper could be published as it is. The authors may have missed some studies but this is not of importance as the researches make their point accurately with included papers.”

   **Answer:**
   We very much appreciate the reviewers’ positive comment on the paper. Missing studies: We have performed an electronic literature search of selected comprehensive databases to identify all RCTs related to the topic of this review. As we focused on injurious falls terminology we only included papers that referred to such terminology in the methods section. Some papers that did not refer to this terminology may therefore have not been included (see reviewer 2, comment 2). To make this point clearer to the reader, we now have clarified our inclusion criteria in the method section as follows: Inclusion criterion number (3) “definition of injurious falls as a study endpoint” has been extended to: “definition of injurious falls as a study endpoint by using the terms “injuries” and “falls”. (see abstract, line 13 and page 5 line 23).
Reviewer 2 (John Campbell)

1. “This paper provides a comprehensive review of randomised controlled trials which have tested interventions to decrease falls and injuries resulting from falls. This is a further paper from the Prevention of Falls in Europe Network (ProFaNE) which has already done excellent work in establishing an agreed terminology and classification for falls, fall prevention interventions and trials.”

Answer:
We very much appreciate the reviewers’ positive comment on the paper.

2. The literature review has been thorough using appropriate methods to ensure all relevant studies have been included. However, it is not clear whether all RCTs reporting fall-related fractures, as opposed to injurious falls, have been included. A number of additional studies (approximately 30 in the community) have reported fracture as an injury caused by a fall. It appears these trials are missing from Table 1. If these have not been included in this review because the fracture was not described separately as an injurious fall then this needs to be clarified in the methods.

Answer:
According to the described methodology we have performed a comprehensive literature review. The search yielded 2089 articles, 1778 were excluded on initial screening as not fulfilling entry criteria, thus 311 were potentially appropriate for inclusion in the review (Figure 1). Of these 311 papers, 270 were excluded, because on closer inspection they did not provide a definition of injurious falls or did not report on injurious falls or did not meet other inclusion criteria. As we focused on injurious falls terminology we only included papers that referred to such terminology in the methods section. Some papers that did not refer to this terminology may therefore have not been included. To make this point clearer to the reader, we now have clarified our inclusion criteria in the method section as follows: Inclusion criterion number (3) “definition of injurious falls as a study endpoint.” has been extended to: “definition of injurious falls as a study endpoint by using the terms “injuries” and “falls”. (see page 5, line 23).

Since we may have underreported the number of papers reporting fracture due to our specific inclusion criteria focusing on injurious falls terminology, we have introduced the following sentence in the limitations section: “We also note that our inclusion only of papers that defined their terms may have resulted in
exclusion of papers where the outcome might be considered self-evident, for example we may have underreported the number of papers reporting fracture if fracture was not defined as an injury (see page 16, line 23).

In addition, some relevant studies may not have been identified as RCTs focusing on fall prevention (inclusion criteria) by the title and abstract screening (see chapter “study selection and data extraction). Others might have been excluded as they did not meet the target population of this review (≥ 65 years).

Although some studies may have not have been included due to the reasons stated above, we have made our point accurately (lack of a methodological standard with respect to injurious falls definitions and methods of collecting and reporting on injurious falls in present RCTs). This has been also stated by reviewer 1 (see reviewer 1, comment 1: “The authors may have missed some studies but this is not of importance as the researches make their point accurately with included papers.”)

3. The authors state as a possible limitation of the paper that they did not review the epidemiological literature for a classification of fall-related injuries. The epidemiological studies will have been reviewed by most researchers prior to the intervention trials. To my knowledge no satisfactory classification exists in the epidemiological literature.

**Answer:**
We agree with the reviewer’s comment about limited methodological standards in the epidemiological literature. It is an important aim to standardize the fall-related injuries also in epidemiological studies. However, as defined in the methods section this review focuses on randomized controlled trials only and therefore epidemiological studies have been excluded.

4. As well as reviewing the classification of injury the authors have also reviewed the methods used in the trials for determining if injury has occurred. The great majority of fall prevention trials have been powered to determine an effect of the intervention on falls not injury. The authors have very usefully calculated the number of participants who would need to participate in trials in which injury of different types and severity was the outcome. Because of the large numbers of participants needed and the difficulties of funding such studies a meta-analysis of existing and planned fall prevention studies would be a more practical approach.
Answer:
We very much appreciate the reviewer’s positive comment on the paper, agree meta-analysis would be a useful approach and make this point in the discussion.

5. The authors have made valuable suggestions about standardizing the methods of determining and classifying fall-related injuries in trials so that, in the future such a meta-analysis will be possible.

Answer:
We very much appreciate the reviewer’s positive comment on the paper.

6. In summary, this is a clearly written paper reporting a comprehensive review of the literature and containing valuable recommendations for future studies. However, the inclusion of studies reporting fractures needs to be clarified.

Answer:
We very much appreciate the reviewer's positive comment on the paper.
As requested by the reviewer we have clarified our inclusion criteria (focus on injurious falls terminology) in the method section and extended our limitations section with respect to underreporting the number of papers reporting fracture. (see reviewer 2, comment 2).

Minor issues that need to be addressed prior to publication.

i) The number of papers given as reviewed and rejected is different in the results in the abstract and the body of the paper.

Answer:
This has been clarified. The number of paper given as reviewed and rejected has been corrected in the abstract and is now identical to the numbers stated in the body of the paper.

ii) Abstract methods description of an electronic search “of various databases” would sound more planned as an electronic search of “selected, comprehensive databases”.


Answer:
The wording in the abstract has been revised as requested by the reviewer (abstract, line 11)

iii) The use of dot points would make table 1 easier to follow

Answer:
Dot points have been introduced in Table 1 as requested by the reviewer.

iv) Table 5 is difficult to follow. “Fallers” needs clarification. Presumably this is the total proportion of participants who had a fall whether causing injury or not. The assumptions for sample size calculation appear to refer to hip fracture only. Do these assumptions apply to all injuries?

Answer:
The word “Fallers” has been clarified by introducing the following footnote below Table 5: “Fallers reflect those study participants who experience any fall (injurious or not injurious) during the study period.”

We have calculated a hypothetical example of sample size requirements for fallers, injurious falls, fractures and hip fractures. We agree with the reviewer that the word “hip” within the following sentence below Table 5 is misleading: “Assumptions for sample size calculation: reduction of hip fracture incidence due to intervention by 15%, statistical power 80 %, significance-level 5 %, two-sided tests.” In our hypothetical example of sample size requirements the effect size has been used for all outcomes. We have therefore revised the sentence below Table 5 as follows: “Assumptions for sample size calculation: effect size -15% with respect to all outcomes, statistical power 80%, significance-level 5%, two-sided tests, not adjusted for multiple testing.”

v) It would also be worth commenting in the paper that a fall-related injury should be classified by an independent person, blind to group allocation.

Answer:
The reviewer mentioned an important issue about blinding the classification of injuries. This has been added to the recommendations section in the discussion by introducing the following sentence “A fall-related injury should be classified by an independent person, blind to group allocation” (see page 16, line 4)
Reviewer 3 (Ian Cameron)

1. This is an important and well written paper. The systematic review has demonstrated conclusively that definitions of injurious falls vary greatly in the published research literature. This has major implications because the lack of a consistent definition means that meta-analyses of studies in which the outcome of interest is injurious falls are likely to be flawed as a result. There are no major compulsory revisions or minor essential revisions. The authors should consider making more explicit recommendations about how injurious falls should be defined. They have completed the definitive review and are well placed to make recommendations that can then be considered by the falls prevention research community.

Answer:
We very much appreciate the reviewer’s positive comment on the paper. Recommendations for defining and categorizing injurious falls have been stated in the discussion of the present review and illustrated by Figure 2. To make our recommendations more explicit for the falls prevention research community, as requested by the reviewer, we now have introduced a Table 6 for our proposed definition of serious, moderate and minor injuries (see page 15, line 21). On the basis of an extensive discussion with several experts in the field of fall prevention (within a web-consensus meeting of the FARSEEING (Repository for the design of Smart and sElf-adaptive Environments prolonging INdependent livinG) project as a ProFaNE follow-up project) we have revised the definitions to be more explicit to the falls prevention research community.

The original definition presented in the text of the paper (“Serious injuries [fracture, head injury, internal injuries] as they are typically documented in charts during hospital admission. Moderate injuries as defined by symptoms [wounds, bruising, sprains, cuts, abrasions] requiring health care attendance. Minor injuries as defined by ADL related limitation due to falls [e.g. reduction of physical activity due to pain or fear of falling] without utilising health care”) has now been revised and is presented in the Table below:

Table 6 Standardized system for categorizing and defining fall-related injuries

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>a – serious injury</td>
<td>medically recorded fracture, head or internal injury requiring accident and emergency or inpatient treatment</td>
</tr>
<tr>
<td>--------------------</td>
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</tr>
<tr>
<td>b – moderate injury</td>
<td>wounds, bruises, sprains, cuts requiring a medical/health professional examination such as physical examination, x-ray, suture</td>
</tr>
<tr>
<td>c – minor injury</td>
<td>minor bruises or abrasions not requiring health professional assistance; reduction in physical function (e.g. due to pain, fear of falling) for at least three days.</td>
</tr>
<tr>
<td>d – no injury</td>
<td>no physical injury detected</td>
</tr>
</tbody>
</table>

We have revised the Figure 2 accordingly:

**Original Figure 2:**

**Figure 2 Standardised modular system for defining injurious falls.**
Definition of serious injuries represents the endpoint with highest accuracy but requires largest sample size due to low incidence of these falls. Definition of moderate and/or minor injuries requires smaller sample sizes but reduces accuracy of data.

Revised Figure 2

Figure 2 Injury categories defined by symptoms and medical care use

[Figure 2 text]: Injury categories of the newly developed system are defined by both symptoms and medical care use. Definition of serious injuries represents the endpoint with highest accuracy but requires largest sample size due to low incidence of these falls. Definition of moderate and/or minor injuries requires smaller sample sizes but reduces accuracy of data (illustrated by left and right arrow).
We have also revised the paragraph in the discussion that is describing the model (see page 15, line 24):

Original paragraph:
According to our findings, a simple modular system of categorising serious, moderate and minor injuries by symptoms and medical care use is recommendable for future RCTs of fall prevention defining injurious falls as an endpoint (Figure 2). We propose a model where high accuracy of data recording is reached by defining serious injuries (fracture, head injury, internal injuries) as they are typically documented in charts during hospital admission. Moderate injuries are defined by symptoms (wounds, bruising, sprains, cuts, abrasions) requiring health care attendance. ADL related limitation due to falls (e.g. reduction of physical activity due to pain or fear of falling) without utilizing health care is classified as minor injuries. Accuracy of moderate and minor injurious falls data is lower as the definition of injury becomes entangled with the type of and availability of care and factors that influence care-seeking behavior, including personality, pain tolerance, and anxiety [32]. However, research on falls causing minor injuries has been highlighted as an important issue as they have also serious consequences such as depression, fear of falling and activity restriction [14].

Modules can be chosen for defining specific types on injurious falls depending on the research question and sample size calculation requirements. Ideally, data obtained in RCTs should include all modules. Modules of medical care use (hospital admission, medical care use, no medical care) can be used for focus on cost calculation. Each of the modules can be used independently as it is characterised by a standardised definition.

Revised paragraph:
According to our findings, a comprehensive, standardized system for categorising and defining serious, moderate and minor fall-related injuries by both symptoms and medical care use is recommendable for future RCTs of fall prevention (Table 6, Figure 2).
Categories can be chosen for defining specific types on injurious falls depending on the research question and sample size calculation requirements. Each of the categories can be used independently as it is characterised by a standardised definition. Ideally, the injuries in each category should be reported even if a specific study is not powered to detect effects. Reporting all injuries will prevent an outcome bias and the data will be available for future meta-analysis. Data of medical care can be used for focus on cost calculation. A fall-related injury should be classified by an independent person, blind to group allocation. Accuracy of moderate and minor injurious falls data is lower as the definition of injury becomes entangled with the type and availability of care and factors that influence care-seeking behaviour, including personality, pain tolerance, and anxiety [32] (Figure 2). However, research on falls causing minor injuries has been highlighted as an important issue as they have also serious consequences such as depression, fear of falling and activity restriction [14].

We have revised the conclusions accordingly (what this study adds, see page 17, last dot point):

Original paragraph:
• Based on our results we recommend use of standardised methodology in future randomised controlled trials including a modular system for defining injurious falls and standardised methods of collecting and reporting on injurious falls.

Revised paragraph:
• Based on our results we recommend use of standardised methodology in future randomised controlled trials including a comprehensive system for categorising and defining injurious falls and standardised methods of collecting and reporting on injurious falls data.
In addition, we have extended our recommendations on the basis of the suggestions of the other reviewers. We have introduced the following sentences:
- “A fall-related injury should be classified by an independent person, blind to group allocation” (see page 16, line 4) (see reviewer 2, comment v).
- “Ideally, the injuries in each category should be reported even if a specific study is not powered to detect effects. Reporting all injuries will prevent an outcome bias and the data will be available for future meta-analysis.” (see page 16, line 1) (see reviewer 4, comment 5).

Reviewer 4 (Catherine Sherrington)

1. This is a very useful review which makes an important contribution to the field and is likely to be a highly cited paper. The manuscript is clearly written.

   Answer:
   We very much appreciate the reviewers’ positive comment on the paper.

2. It is also likely that the population/setting of the study would influence the rate of injurious falls and the proportion of falls that are injurious. This could be acknowledged in the discussion of variability in included studies.

   Answer:
   We agree with the reviewer’s comment that some of variability between study outcomes might be related to the population/setting of the study. However, our results clearly demonstrate that the definition substantially influences the proportion of injurious falls and thus hampers the comparability of study outcomes. This is e.g. shown in the discussion (subsection “Injurious fall definition”) by the following example: “For example, Lord [46] defined bruises, strains, cuts and abrasions, back pain and fractures and reported 63.5% of all falls were injurious. In contrast, Becker included only radiologically confirmed fractures, resulting in 4.5% of injurious falls.”
   To discuss a likely influence of the population as suggested by the reviewer we have now added the following sentence following the above mentioned example: “Although some of the differences between studies might be explained by the
different populations and settings, the high proportion of injurious falls in the Lord study is most likely due to the inclusion of falls that caused minor injuries [46].

(see page 11, line 27).

3. I suggest a reordering of the manuscript so that the results / tables regarding the methods of collecting data on injurious falls appears prior to the section on the proportion of falls that are injurious.

Answer:
As suggested by the reviewer, we have now reordered the manuscript so that the results / tables regarding methods of collecting data on injurious falls appears prior to the section on the proportion of falls that are injurious.

4. In the limitations section the statement that the present review includes most relevant high-quality studies could be modified as the use of the word “most” implies that the authors are aware of missing studies and “high quality” is potentially misleading as RCTs are of differing methodological quality and this has not been assessed in the current review.

Answer:
We agree with the reviewer’s comment. We have therefore revised out limitation section as follows: “Only RCTs in fall prevention were included in the present review and therefore it reflects the methodological status in this specific research area. We are aware that by this pre-selection relevant data, including epidemiological sources, may not have been considered.” (see page 16, line 20)

5. I suggest that a further recommendation could be that all falls trials should report injurious falls even if they are not powered to detect effects on this outcome. This data can be used in future meta-analyses. I think there is probably outcome reporting bias in the current literature as authors may be tempted to only report on injurious falls if the results are in the “correct” direction. I think this is evident in the latest Cochrane review of fall prevention interventions in the community as the pooled estimate of the impact of exercise on fractures is much larger than the pooled estimate of the impact of exercise on falls.

Answer:
The reviewer mentioned a very important point about an outcome reporting bias if injurious falls events are not reported due to limited statistical power. We have included this point into our discussion as follows: “Ideally, the injuries in each category should be reported even if a specific study is not powered to detect effects. Reporting all injuries will prevent an outcome bias and the data will be available for future meta-analysis.” (see page 16, line 1).

6. I noticed a typographic error in the abstract “the aim or this study”.

Answer:
This typographic error has been corrected in the abstract.

Further revisions made in the manuscript to meet the formatting criteria of *BMC Medical Research Methodology*.

- Title page, authors' affiliations: The city of each author has been added.
- Title page: The sentence “authors share first authorship” has been changed to “These authors contributed equally to this work” according to the BMC Journal guidelines.
- Page 18, author contributions: We have now inserted initials instead of full names.
- Page 18, competing interests: The competing interests statement has been worded according to the journal guidelines: “The authors declare that they have no competing interests.” (Deleted wording: No conflicts of interest have been reported by the authors or by any individuals in control of the content of this article).