Reviewer’s report

Title: Reporting of complex interventions in clinical trials: development of a taxonomy to classify and describe fall-prevention interventions.

Version: 1 Date: 2 February 2011

Reviewer: Geeske Peeters

Reviewer’s report:

General comments
In the past decades, many RCT’s have studied the effectiveness of a range of fall prevention programs. The outcomes of the studies varied greatly and even systematic reviews show different results. Part of this is explained by the heterogeneity in the interventions, analysis and reporting of the outcomes. This paper offers a tool (taxonomy) to characterize both published and future intervention studies and to promote uniformity in reporting the results. I anticipate that the taxonomy described in this paper will become a valuable instrument for researchers in this field and may be a key to advance fall prevention research to the next level.

I highly encourage the publication of this paper in an open access paper, to enable easy access for all researchers and health practitioners in this field irrespective of where they work (i.e. position, setting, country, facilities).

The paper is well written, certainly given the complexity of the material, but there are a few issues I would like to address.

Specific comments -> Minor Essential and Discretionary revisions

• paper
  Table 1 – Please check if the questions listed in this table are correctly phrased. I am not a native speaker, but some of the phrasing seemed a bit odd to me.
  Question 1: Did you mean “i.e. is the taxonomy complete” rather than “completeness”
  Question 2: I don’t understand the second question.
  Question 8: I believe this question is important for interpreting the outcome of the taxonomy, but not for the development of the taxonomy.

Discussion/Table 2: domains of the taxonomy – Please discuss the importance of the distinction of the four domains. What is the added value of each of the domains (e.g. selection criteria and recruitment may be overlapping)? Why does the taxonomy not include questions about the effectiveness of the intervention?

The paper doesn’t discuss the manual. How was the manual developed? Were raters asked for feedback regarding the manual (clarity, ease of use, completeness)?
Please discuss in the paper how this taxonomy should be used: does it replace the CONSORT guidelines or should it be used in addition to this (or other) guidelines?

**manual**

Introduction (page 2) – Tips on using the taxonomy: Please add here how the taxonomy should be used in regards to other guidelines such as the CONSORT guidelines.

Table 1 (page 3) – Domain 2 – Primary site of delivery: “the site at which the majority of the intervention is delivered or targeted”

Approach (page 7) – primary selection criteria – Screening tool: Many tools are available, did you deliberately decide not to specify this? What are the implications if selection criteria based on tools with different aims (e.g. single fall risk, multiple fall risk, fracture risk) are categorized as one group?

Base (page 8) – The manual uses the heading “Case Identification/Primary Site of Delivery”, whereas the taxonomy uses the heading “Recruitment/Main site(s) of delivery”. To avoid confusion, I think it is better to use the same terminology in the headings in the manual and taxonomy.

**taxonomy**

Approach – primary selection criteria – Age group: only a lower limit for age range is asked, but some studies do have an upper limit. Would it be relevant to add?

Approach – primary selection criteria – Selected ethnic group: what if no specific selection criteria regarding ethnicity were used, but because of the setting/country, all participants are from one specific ethnical group?

Descriptors – Control group – medication – The control group could be given other drugs (according to existing protocol/usual care) or lower/different doses. Maybe add a free text option here for further specifications?

**Level of interest:** An article of outstanding merit and interest in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

'I declare that I have no competing interests