Reviewer's report

Title: Falls Assessment Clinical Trial (FACT): design, interventions, recruitment strategies and participant characteristics

Version: 1 Date: 23 February 2007

Reviewer: Gabriele G Meyer

Reviewer's report:

General
Thank you very much for giving me the opportunity to comment the manuscript. The paper is well written. However, I have some concerns which should be considered in the revision of the paper.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)
1) The question posed is of importance. A multifactorial intervention aimed to reduce recurrent falls has been delivered within a high risk population of community dwellers. This paper describes the design and methods, and results of recruitment and randomisation. The paper apparently also describes a deviation from the original study protocol in terms of an adapted recruitment process. This point should be made clearer.
2) I would not recommend mentioning hormone replacement therapy as a fall preventive option (introduction, page 4) since it is well known that the adverse effects outweigh possible benefits (4).
3) The recently published paper by Cumming et al. (1) should be considered.
4) One of the exclusion criteria mentioned in the study population section (page 6) is dementia. In Figure 2 the authors state that three persons were excluded due to poor memory. It is not specified how the exclusion criterion has been operationalised. In Table 1 dementia screen is mentioned as one targeted neurologic examination. Why do the authors look for dementia when the condition is already an exclusion criterion? How is the caretaker's awareness of cognitive deficits defined?
5) The pre-planned fall screening strategy used a simple question (page 6, section recruitment). It remains unclear whether patients entering the practice were fully informed about the study before the application of the screening. The second recruitment procedure should be specified. Did eligible patients get a post-paid envelope or were they contacted by telephone?
6) The authors should insert a statement how the randomisation sequence was implemented (by external telephone or by mail).
7) The authors should also highlight whether the study groups were treated equally in terms of prompt implementation of the fall prevention programme and optimised standard care, respectively. A time gap between the two groups could have influenced the outcome.
8) A statement how informed consent of participants was gathered should also be inserted.
9) The authors declare that the research nurse collecting outcomes was blinded to study group allocation (page 6, randomisation and blinding). However, since participants were assessed at home and home modification is part of the intervention it is highly unlikely that blinding could be hold up. The authors should specify which efforts they undertook to ensure blinding of the outcome assessing nurse.
10) The authors should point out if the nurse co-ordinator differs from the outcome collecting nurse (page 8).
11) An explanation whether fall-related injuries and hospital admissions are externally verified should be inserted (page 7, section secondary outcomes).
12) The intervention group approach includes the recommendation of supplementation of vitamin D and calcium. Bisphosphonates are part of the bone health intervention strategy, too. However, the Women's Health Initiative including more than 36,000 postmenopausal women did not demonstrate a fracture preventive benefit through vitamin D and calcium supplementation, but kidney stones increased statistically significant (2). Therefore, it is of major concern that adverse effects have not been documented. Especially for bisphosphonates upper gastrointestinal disorders and other adverse effects (3) should have been documented.
13) The control group approach remains unclear. What is the intention of the social visit by the accredited visitor? What kind of written information is provided (topics, extent, availability)?
14) The sample size calculation is based on the outcome "person with at least one fall". However, within the methods section (page 6) fall events rather than persons with falls are defined as primary outcome measure. This should be clarified.
15) The Figure 2 indicates that a pilot study has been performed. This information should be given in the
manuscript including information on the aim, duration and setting of the exploration.
16) Table 2 does not seem to be of interest for the reader. Since the groups displayed do not differ in any terms, selected numbers could be reported within the text.
17) In Table 4 the range of the SF-36 subscales (0-100) should be mentioned. The authors do not explain why they only present four out of eight subscales of the SF 36. It also remains unclear why they present 95% confidence intervals rather than standard deviations. The comparative New Zealand sample should be described briefly within the methods section. Presentation of p-values would be of interest.

References
3)Mortensen M, Lawson W, Montazem A. Osteonecrosis of the jaw associated with bisphosphonate use: Presentation of seven cases and literature review. Laryngoscope 2007; 117: 30-4

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)
18) Although a complex intervention comprising assessment and individually tailored intervention has been provided the authors call their study a pragmatic trial. I think this term should not be used because of the major experimental efforts.
19) Figure 1: The exact number of randomised individuals should be inserted since these figures are already available.
20) Table 1 indicates provision of bladder training in case of bladder incontinence. Could the authors mention a reference which refers to the intervention provided? I wondered which kind of dietary has been advised. This can apparently do not mean recommendation of vitamin D and calcium since this intervention is mentioned at the following page as a measure to increase bone health. I am not aware of any evidence-based dietary intervention to reduce falls. What do the authors mean by “modification of salt restriction” (Table 1)?
21) If Table 2 remains, please insert a comma in the first line presenting the age of the waiting room group. Units related to the displayed characteristics should not be mentioned in brackets, e.g. “Age (years)”. The table would be easier to read if a comma is used, e.g. “Age, years”. I think the explanation concerning the range of the scales presented should be mentioned as a footnote.
22) I suggest formatting of Table 3 according to my suggestions for Table 2. Numbers reported in this table should be standardised (at some places three decimal places are reported, at other places only two). The abbreviation “CVA” should be explained.

Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article whose findings are important to those with closely related research interests

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.