Dear Dr Saltman

Re: MS 2008769661126162
Falls Assessment Clinical Trial (FACT): design, interventions, recruitment strategies and participant characteristics

Thank you for the detailed and constructive reviews of our paper. We have addressed each point raised by the reviewers and indicate below where each is addressed in the revised manuscript.

We note one reviewer’s concerns regarding ethical aspects of the study but would point out that a New Zealand Ministry of Health appointed ethics committee judged this study to meet all ethical requirements before the study commenced. It is also important to note that usual care as defined in this study is actually the standard in New Zealand since no formal falls prevention pathways currently exist. We have addressed the concerns about describing the recruitment strategies more clearly in the revised version.

This paper describes in detail the multifactorial intervention used in a community-based trial, the design of the trial, and the response rates and characteristics of participants of using two different recruitment strategies to identify older adults at high risk of falling in a primary health care setting. We feel that this manuscript is important and informative for future fall prevention trials – especially those based in primary health care and the community – and to describe the design of the current trial.

Reviewer KH:
We thank the reviewer for his thoughtful summary of our study and its placement in the context of current falls prevention literature.

Major Compulsory Revisions:
1. and 2. Table 3 (now Table 2) and the abstract now report median and inter-quartile range for variables where results were not normally distributed.
Minor Essential Revisions:
1. The falls risk assessment refers to the identification of well known risk factors that can be addressed to prevent falls (or fracture from falls) and is outlined in Table 1. It is not a validated assessment tool.
2. The osteoporosis tool used was one used clinically identifying risk factors such as previous fracture, hip fracture in a parent, smoking status, use of steroids, low body weight, loss of height, early onset of menopause, and heavy alcohol use. It was not a validated tool but based on evidence of risk factors for osteoporotic fracture [1, 2].

Reviewer GM:

Major Compulsory Revisions:
1. The addition of an alternative recruitment method is now described more clearly (P4, last paragraph).
2. We have removed hormone replacement therapy from the list of fall prevention options (P3, last paragraph).
3. We now refer to the recently published paper by Cumming (P4 paragraph 1).
4. We now describe how reduced cognition (or dementia) was determined (P6 paragraph 3). “Poor memory” is changed to “poor cognition” in Figure 2. “Looking for dementia” has been removed from the Table 1 because those with dementia were excluded from this trial.
5. The screening form started with a brief description of the study stating that it was a study about preventing falls and asked firstly whether they would mind answering the screening question about previous fall. It then asked if the person had answered “Yes” to previous fall, would he or she be interested in talking to the research nurse about the study. If the answer was again “Yes”, it asked for their name and contact phone number so that the research nurse could talk to them about the study and to establish whether it was a fall according to the study definition (P6 paragraph 4). The mail-out screening form also asked if the person had had a fall or trip in the last 12 months and if they would like to talk with a study nurse about the study. If so, they could send the form back by post-paid envelope to the researchers. More details are now specified in the Methods (P6 paragraph 4).
6. Details of implementation of randomization have now been included (P7 paragraph 1).
7. Once a participant was enrolled and randomized, names and contact details of intervention participants were forwarded to the community falls and fracture nurse. The nurse would then contact the person to arrange home based assessment. These assessments usually occurred within a month, but with an occasional delay, as she was an existing community-based gerontological nurse with other duties and waiting lists, which is the case in real-life practice (P8 paragraph 3). Names of control participants were forwarded to the researcher who organized home-based visits and a mail-out of falls prevention pamphlets produced by the New Zealand Accident Compensation Corporation for falls prevention in older adults. These visits usually occurred within one month (P9 paragraph 2).
8. Details of obtaining informed consent are now outlined on P6, paragraph 4.
9. Blinding is very difficult in this sort of trial and cannot be assured. We agree that home alterations may have been evident in some cases (P7 paragraph 1). However, the two research nurses undertook assessments at baseline and 12 months follow-up on 312 participants, so remembering which alterations had been present at baseline and which were new was not very likely. Also, research nurses were undertaking questionnaires and health, strength and balance measures – not looking for home alterations. Participants
were informed at the start of the trial that the research nurses were not to know which arm they were in. These assessments were not the primary outcome of the trial. The primary outcome was falls recorded on monthly fall calendars that were sent in by participants.

10. We state that the research nurse collected outcome data (P7 paragraph 1) and remained blind to allocation of intervention and that the intervention was delivered by a community-based falls and fracture nurse coordinator – that is, these are two different people (P8 paragraph 3).

11. Information about injuries and hospital admissions were obtained by telephone interview from the participant or their family contact by self report. In as many cases as possible we confirmed reports from hospital records (with the participant’s consent) (P7 paragraph 2).

12. When this study commenced standard recommended practice was to offer bisphosphonates to those with documented osteoporosis on DEXA scan. This study was not deviating from accepted practice or testing the side effects of currently approved medications. The intervention (falls and fracture nurse) screened for osteoporosis using a short questionnaire, and for those at risk, she prompted family physicians to offer a DEXA scan. The action taken according to the result of the scan was up to the family physician, as was the decision on offering calcium and Vitamin D supplementation or a bisphosphonate. (ie: it was not the decision of the falls and fracture nurse). The family physicians in the area had received continuing medical education on management of osteoporosis and were sent a handout written by local clinical gerontologists based on current evidence.

13. The social visits were offered to control participants to adjust for the social contact received from the falls and fracture nurse and exercise initiator. The fall prevention information included a standard pamphlet produced by the New Zealand Accident Compensation Corporation for use in primary health care for the prevention of falls in older adults (P9 paragraph 3).

14. The analysis is at the individual level, examining fall rates and controlling for clustering and individual confounders. This is now clarified (P9 last paragraph and P10, first paragraph). Sample size estimations used results available from the PROFET trial.

15. The aims and duration of the small pilot to check the logistics of the intervention protocol, assessment and referral procedures is described (P8, last paragraph).

16. Table 2 has been removed and replaced with selected results presented in the text (P11, paragraph 2).

17. Table 4 has been removed, as information to complete the comparisons and descriptions suggested by the reviewer are not available for the New Zealand data.

**Minor Essential Revisions:**

18. “Pragmatic” trial has been replaced with “community-based” or “primary health care” trial (P4, last paragraph and P5 paragraph 2).

19. Figure 1 shows the design flow, not the results. However, we have included the number randomized to each group.

20. Nutrition assessment has been removed from the falls assessment protocol (Table 1) as it was included at the recommendation of a participating clinician involved in the design of the study but is not related to evidence for falls prevention, and did not result in specific referrals in practice. We agree that there may be a correlation between incontinence and falls, but we are not aware of evidence that suggests intervention reduces falls risk. Similarly, salt restriction for raised blood pressure is not related to falls prevention, and was removed from Table 1.

21. Table 2 has been removed.
22. Table 3 has been renamed Table 2 and has been reformatted according to reviewer recommendations.

**Reviewer DH:**

**Major Compulsory Revisions:**

1. **Ethics:** A New Zealand Ministry of Health appointed ethics committee judged this study to meet all ethical requirements before it commenced. It is also important to note that usual care as defined in this study is the standard in New Zealand since no formal falls prevention pathways currently exist. A community-based trial was indeed necessary it was not known, especially at the time of trial commencement, whether applying evidence-based multifactorial falls prevention interventions in addition to usual care in primary health care would be effective in preventing falls. Interestingly, a very recently published article found that a comprehensive risk assessment and referral for physical therapy and to other health providers was not effective in reducing falls [3]. The results of the trial would not support all older people receiving comprehensive assessments coupled with a plan to deal with each risk factor in a systematic way to prevent falls. This is the same hypothesis we are testing.

2. **Background:** The comment that refers specifically to New Zealand rates of attendance of older adults to primary care has been removed (P3 paragraph 1). We have shortened the background somewhat, but include aspects we consider important background to the choice of intervention and approach of the trial. We include a description of the PROFET trial as the intervention used in this trial was based on the PROFET intervention but applied in primary health care. Thank you for suggesting the articles about recruitment of frail older adults. Reference to these are now included (P4, last paragraph and P5 paragraph 1).

3. **Definition of terms:** “Pragmatic” trial has now been changed to “community-based” and “primary health care” trial in the text (as mentioned above). “Primary care” referred to primary health care or care delivered in the community by family physicians. We have changed this term to “primary health care” throughout the text. The reference to size of practice has been removed, as the decision to add a different recruitment strategy was made early in recruitment, and practices where both or either recruitment strategy were used varied from 2-doctor to 5 or 6-doctor practices. (The initial practice had 6 doctors). An “accredited visitor” is a visitor who has undergone checks as a safe and suitable visitor to undertake visits for older people in their homes (e.g. all had undergone police checks and either worked for the community-based agency “Age Concern” or were nursing students from a local University) (P9 paragraph 3).

4. **Methods:** Screening for dementia is now covered (see above). “Unstable or progressive medical condition” is a term we often use in trials to allow exclusion of those the family physician considers to be medically unfit to participate in the intervention. This mimics real life conditions, as these doctors would only refer patients to such programmes if they considered them to be medically fit to participate. The difficulty in not being able to define accurately the exclusion criteria in such community-based trials is weighed against the improved generalisability of allowing every-day clinical judgment (i.e. who would actually receive such a programme in every day practice). Details of the form used in the waiting room are covered (see above). The mail-out was sent by the participating practices primary care administrative organization with consent from each family physician. The post-paid replies were sent to researchers. The letters contained a short summary of the aims of the study and invited those who had had a fall or trip in the last 12 months to reply if
they were interested in talking with a study nurse about the study; similarly with the screening form used in the waiting rooms of practices.

Patient registers from practices are updated regularly as the New Zealand bulk funding model for primary health care requires current information on patient registers. However, we agree that there may have been a few who had moved or died since the last practice register update. As we did not send out the letters ourselves, we do not know the number of returned forms. However, we can assume it to be a very small number compared with the number of letters sent. The letter was not piloted but was developed in consultation with family physicians and approved by the primary health organization involved and representative family physicians prior to its use.

5. **Results**: The rationale for initiating the second recruitment strategy was based on subjective observations of the rate of recruitment. The description of this, therefore, has been moved from the Results to the Methods section. However, the comparison of recruitment rates and characteristics of participants from the two recruitment methods was more objective and is reported in Results. We now report the statistical difference in recruitment rates of the two recruitment strategies in the Results section and have undertaken two sensitivity analyses around the assumption of fall rates (Page 11 paragraph 1).

6. **Discussion**: The conclusion about the two recruitment strategies has been amended to suggest that the recruitment rate in the waiting room was higher than the mail-out (the reference to size of practice was removed as we do not have objective data to support that). We also now state that the estimation of a 40% participation rate may be imprecise (P13 last paragraph and P14 first paragraph).

**Minor Essential Revisions:**

1. **Methods**: Lowering of the study inclusion age for Pacific and Maori people in clinical trials is common practice in New Zealand. It was in fact recommended by the Maori and Pacific health groups we consulted with, and such consultation and incorporation of the advice is a requirement of all New Zealand ethics committees. The unit of analysis is individual as the intervention (nurse assessment and referral) was home based and randomization was by individual. (The unit of analysis should be the same as unit of randomization). However, we do include primary care practice in the model as a cluster variable to allow for the study design (P10, first paragraph). The waiting room recruitment did involve the placement of the research nurse in the waiting room. New Zealand ethics committees require that potential participants for clinical trials are not approached initially by research personnel. Therefore an option was the receptionist handing out the screening form at the desk. However, the presence of the research nurse in the practice rooms prompted the receptionist, and the research nurse was present should anyone want to discuss the study on the spot, which was common. Issues of blinding and determination of blinding are discussed above. There was only one fall assessment nurse coordinator. She was a nurse with experience in gerontology, but was up-skilled by clinical research personnel with experience in this area. She also visited a community-based fall prevention programme in Australia to observe their techniques and approaches. She could contact the family physician of the participant, and frequently referred the participant back to their attending family physician with any queries or identified fall risk factors. She could also contact a member of the research team for advice, although this happened only rarely. The research team included a geriatrician, four family physicians, an experienced nurse and an experienced gerontological researcher. However, the falls assessment nurse coordinator was not permitted to contact the research nurses about any participant, as research nurses remained blind to allocation of intervention. Three geriatricians from
the local hospital were also involved in advising on the design of the intervention and were available should there be issues. However, the falls assessment nurse coordinator liaised primarily with the attending family physician. The nurse could make referrals to the optometrist, podiatrist, physiotherapist, exercise programme or occupational therapist to assess and address the identified issues, and the attending family physician was sent copies of all referrals. All other identified risk factors were referred back to the attending physician, including for consideration of DEXA scan. Table 1 summarises the basis for the intervention, but the nurse had a clinical recording sheet where findings and actions taken were documented (and faxed to the attending physician and other health professional where a referral was sent). There was a low threshold for referral back to the family physician and these referral rates will be reported in the final results paper.

2. **Results:** The ethnicity question in the baseline questionnaire (including the ethnic categories listed in the text) was from the New Zealand census. Use of the census categories was recommended by Maori advisors and ethics committees at the time of the application for ethical approval of the study. Europeans who are not New Zealand born Europeans may identify with another country (e.g. Dutch).

3. **Figure 2:** The third box from the top on the right has been amended to show the estimated number of those who had fallen (i.e. 811).

**References:**


We look forward to your response to our revised paper.

Yours sincerely

**M Clare Robertson, PhD**

Research Associate Professor