Reviewer's report

Title: Combined effects of functionally-oriented exercise regimens and nutritional supplementation on both the institutionalised and free-living frail elderly (double-blind, randomised clinical trial)

Version: 2  Date: 2 March 2008

Reviewer: Dawn D Skelton

Reviewers Comments:

With the predicted rise in numbers within the oldest segment of the population, the authors have understandably chosen to look for ways to enhance quality of life and mobility in this often neglected clinical research group. Their aims, to find an intervention that is easy to apply and cost effective, is a laudable one. It has been known for some time that functional exercise is more effective in terms of improving mobility than choosing a single mode of exercise, such as strength training. However, the effect of the addition of a nutritional supplement has been less studied, particularly in conjunction with functional exercise rather than strength training alone. This study was unable to demonstrate that nutritional supplement enhanced training in general (as walking function was only improved only in the group that did functional and standard exercise plus supplement but not in the group who had functional and strength exercise plus supplement) but did seem to show that strength training did not in general enhance the effects of the programme on functional ability, contrary to previous studies. Some of this discrepancy may be in the definition of what constitutes strength exercise and what constitutes standard exercise. The authors point out that there is a need for more research and I would suggest that future trials should be considering exercises with known efficacy with and without nutritional supplement. Further work is also needed to evaluate the ease of implementing such interventions and the cost-effectiveness of these interventions in terms of Quality Adjusted Life Years (QALYs). This particular intervention is extremely labour intensive as it involved one to one physiotherapist delivered exercise (but ensured compliance with supplement) and perhaps the outcomes could be compared with the costs of delivering such an intervention in small groups with associated transport costs as these would not be delivered in the persons own home or nursing residence.

1. Is the question posed by the authors well defined?

The question is well defined but not answered by the current research data, therefore the question needs tightening. The main question posed relates to seeking out an easy-to apply and cost-effective way of addressing multiple functional deficits in frail older people yet the data only supports exercise effectiveness, not ease to implement or cost to implement.
2. Are the methods appropriate and well described? The methods used for exercise effectiveness are appropriate and well described.

3. Are the data sound? Yes.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition? Mostly, though it would be relevant to give reasons for why people were not eligible or dropped out of the study.

5. Are the discussion and conclusions well balanced and adequately supported by the data? There is a need to review the conclusions with the data in mind and adhering to the stricter question of exercise effectiveness rather than ease or cost to implement. There is also a need to review the discussion with a less critical review of other authors interventions and more on how the current data support the use of such exercise interventions in clinical practice.

6. Are limitations of the work clearly stated? Yes.

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished? Yes.

8. Do the title and abstract accurately convey what has been found? The abstract needs reviewing to ensure clarity of results.

9. Is the writing acceptable? Yes.

Major Compulsory Revisions:

1) Abstract: The main question posed in the Background seems to concern the ease to apply and the cost effectiveness of an exercise intervention that could be applied nationally. The data does not support this question, it asks which of two combined exercise interventions (standard exercise and functional exercise vs strength exercise and functional exercise) is most effective and whether nutritional supplementation enhanced the effects. The abstract and the introduction sections need amending.

2) Abstract: The conclusions need addressing. I do not feel that the conclusions address the results. You state that "only multifactorial intervention (FOE plus supplementation) has clear potential for appreciably improving overall functional status in the frail elderly in terms of individual walking capacity and muscle strength yet the data as I see it do not give that impression. Below is a simplified table of the results:

Exercise Regimen and nutritional supplement Strength Outcomes Functional Outcomes
I PRE+FOE+ NS â## No change
II PRE+FOE+ Placebo â## No change
III SE +FOE+ NS No change â##
IV SE +FOE+ Placebo No change â##
In fact, balance improved more in the placebo group of the SE+FOE. So I feel you need to revisit and rewrite the conclusions of this study. Perhaps a clearer explanation of the main differences between SE and FOE would help the reader but the role of nutrition is less clear.

3)

Minor Essential Revisions:

1) Abstract: Methods section rather than giving the test equipment information, it is more important to the reader to know the muscle groups tested (1RM). It is also necessary to add the length of the intervention and frequency of delivery.

2) Abstract: Results section please add number of subjects completing the intervention/study.

3) Background: This section has many very long sentences (over 6 lines long) which make clarity difficult. Please shorten sentences in this section. Suggest the second paragraph becomes the first paragraph.

4) Methods: Study Population please give an indication of when considering fractures as an exclusion criteria and whether people were excluded if they had EVER had a cerebral incident. In the UK, this would mean this intervention would be unavailable to a very large proportion of the oldest population. Please break down the n=80 to show numbers in nursing home and in community.

5) Methods: If the subjects were randomly assigned into the four groups why do you state as far as it was deemed practicable/practical?. Please explain.

6) Methods: Baseline characteristics EKG should read ECG? The last sentence saying there were no differences should be at the start of results section?

7) Methods: Overall assessment of physical function please state how many times the functional tests were done and whether an average or best result was used in analysis. Same for the strength measures. On the last sentence of muscle strength assessment you discuss muscle strength was assessed in four different lower limb positions, how was this done (on HÖGGAN?) and how was this compared to the start resistance of the bands?

8) Methods: Structured exercise sessions please explain how the authors assessed the exercise to be high intensity. I can see that the strength training was (80% of 1RM) but how did they assess the functional exercise or the standard exercise? Please also explain how they kept the exercises at 80% 1RM if the HÖGGAN was only used in the baseline assessments? What was their progressive resistance training protocol?

9) Statistical Analysis: I wonder if the use of a two way ANOVA might have been better to assess the role of PRE vs SE and Nutritional Supplement vs Placebo is a more sound statistical approach, particularly as then the home environment
(nursing home vs community) and age could then have been considered as confounding factors. The sentence â##since all parametersâ# of a 0-2 scaleâ## confuses me as Strength is measured on a continuous scale and so is distance walked etc? please clarify.

10) Results: The Figure shows that 11 people were excluded from the assessments after the intervention â## more details about why they were excluded are necessary.

11) Results: The second sentence of the first paragraph is not well explained as if the sentence was correct, all groups I to IV would have seen improvements.

12) Results: Primary Outcomes section - I would want to see Group I vs Group II and Group III vs Group IV â## though this would be picked up by a different statistical approach (see above). The second paragraph states that notable improvements in mobility were seen yet there was only a change in 6MWT not Tinettis gait score?

13) Results: Secondary Outcomes section â## the first sentence confuses me as there is mention of distance covered by over 35 metres yet the 6 meter walk test is used â## please clarify. The second paragraph of this section belongs in the discussion and needs reconsidering as FOE was in all groups anyway.

14) Table 1: Would be useful to have % in nursing home and % in the community within the table.

15) In all Tables: Tinetti Total Score, Tinetti Balance Score and Tinetti Gait Score is used, but in the text there is reference to Tinettis Performance Oriented Mobility Assessment Test (POMA) â## this is confusing to the reader.

16) Discussion: Please discuss the 12% drop out rate (80 out of 91 starting) during the relatively short intervention of 7 weeks compared to other interventions of longer duration but less frequency that have similar drop out rates. Please also discuss why the authors chose 5 days a week for the intervention (and wanted to do 7 days a week) when most exercise interventions have been shown to be effective in this aged population when done 3 times a week and in fact ACSM guidelines (not referenced) suggest that older people need rest between exercise for the body to be allowed to repair and ready itself for the next bout of exercise? It would be useful to reference the ACSM guidelines on exercise for older people as this discussed adequate warm up and components of fitness suggested to be part of a structured exercise programme for seniors. The general prescription of moderate physical activity for health is a recommended 30 mins of moderate physical activity on at least 5 days of the week so perhaps this is what the authors were aiming at with the intervention, but if so, why choose high intensity strength training (which is above moderate) and why aim for 45 mins per session? Surely this will make the intervention more costly (in terms of 1 to 1 delivery) and mean that the population are less likely to adhere to the programme. Within the discussion perhaps the authors could also explain why the exercise warm up started in the recumbent position and whether there was any incidence of postural hypotension following and also whether there was any cool-down at the end of the session? There needs to be some discussion about chances of long term behaviour change and adherence to
exercise following such a short intervention (7 wks) when most studies have shown behaviour change takes longer in terms of exercise. Finally, considering the exercise intervention was aimed at improving mobility and consisted of functional exercises why were the exercises performed seated? Some clarity as to the decisions made as to the type/ frequency/ duration/ intensity will make this study easier to understand.

17) Discussion: There is again mention of easy applied and cost-effective solutions yet there is no time/staff or cost data in this paper perhaps remove and discuss effective interventions.

18) Discussion: In the UK and in the USA there are exercise on prescription schemes that GPs can refer people into, this is a practical way of ensuring there is a way of physicians helping to slow the functional decline in older people, perhaps some reference to these published schemes? Particularly as there has been some costings against such schemes.

19) Discussion: The authors note the daunting task of trying to quantify approaches that discuss the tailoring of exercise to the individual, yet in falls prevention exercise interventions we know that the ONLY ones that work are ones that are tailored to the individuals ability and progressed to suit the individual (Cochrane Review). Perhaps some further discussion on this to clarify the authors position?

20) Discussion: Much of the discussion reads a bit critically of other studies methods and approaches, I am sure this was not intentional but perhaps the contents of the discussion could be reviewed? Discussion of gait speed vs distance covered is not really appropriate as older people need both to be optimal to maintain independence? There is discussion about compliance to nutritional supplementation being better, is this just because the physiotherapists were more directive and were in the patients homes telling them to drink the supplement whereas in other trials people had to take the supplement undirected? There is no need to criticise other authors only giving data on one leg following training, if the training was using both limbs there is no real need to give both, many trials give average of both legs and not both legs separately.

21) Discussion - Some relevant studies are not included (eg Skelton 1995 strength training programme that did not improve function and Skelton 1996 strength and functional exercise that did improve function; ACSM guidelines and recent meta-analysis of exercise to improve balance Howe 2007, Cochrane review).

22) Conclusions: Need revision considering above comments.

Discretionary Revisions:

1) Abstract: Methods section suggest replace embraced with included.

2) Background: It would be useful to have a reference next to the comment that functional deficiency is expected to take a significant portion of medical practice time. It would also be useful to have a reference for the sentence that loss of strength and function with advancing age is reversible. The term sense of
balance is misleading, perhaps should just say balance.

I confirm that this report may be posted on the website along with the article and other reviewer's reports.

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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: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare that I have no competing interests