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:** 16 April 2008

**Reviewer:** Michelle Miller

**Reviewer's report:**

**MAJOR COMPULSORY REVISIONS**

1. The tone of the article is disrespectful of other work in this area while overestimating the quality of the study reported. In particular the authors are encouraged to revise sections describing the work of Rosendahl and Bunout. In addition the authors should acknowledge the limitations of the study reported, namely lack of economic analysis to determine cost effectiveness, a one dose fits all approach to nutrition supplementation, non intention to treat analysis and apparent lack of a power calculation.

2. The manuscript requires revision to remove ageist remarks and attend to complicated, long sentences.

3. In addition, there needs to be some discussion of the workforce implications of requiring a physiotherapist 5 days per week to deliver what appears to be a relatively simple program. Perhaps a further recommendation might be to trial a similar regime using allied health assistants rather than physiotherapists.

4. Further consideration should be given to the nutritional status of frail older adults and assessment/prescription/monitoring by qualified staff eg. Dietitians or dietetic assistants. The nutritional needs of older frail adults is poorly understood and best practice would suggest more attention be given than a one dose fits all approach.

5. Adherence needs to be more comprehensively described for both the exercise and nutrition interventions. How was nutrition adherence measured and confirmed in free-living participants?

6. Description of the assessment of nutritional intake requires revision. Appears as though a 7 day food record was completed for caloric intake initially but there are no details on why these data were collected. It also appears as though daily food records were completed for the duration of the study. This is a highly burdensome method and the data have not been sufficiently utilised. It is unclear why it was collected as the nutrition supplementation was a one dose fits all approach. At the very least the authors should have the capacity to comment on what % of requirements were met by the supplement vs voluntary oral intake alone and overall whether the dietary intervention resulted in participants achieving sufficient energy etc to meet or exceed estimated requirements. These data would also be useful to determine whether the supplements 'supplemented'
the diet or replaced voluntary oral intake. What food composition database was used? How were the multiple days of intake data analysed?

7. Remove all interpretative statements from the results section. The data should be allowed to speak for itself. Suggest the revision of this section to (1) describe the sample (refer to key messages from Table 1); (2) primary outcomes – insert the data to demonstrate the magnitude of the muscle strength gains for both resistance training groups and the lack of translation into mobility outcomes, highlight the SE + nutrition group achieved mobility gains without gains in strength. The authors should attempt to describe this inconsistency in the discussion rather than critiquing other work. (3) secondary outcomes – the data presented here appear to highlight within group achievements. It could be considered more useful to present other between group differences such as body composition (also change in overall nutritional status – eg. MNA), changes in mobility aids, health service utilisation outcomes, mortality etc. (4) a section on adherence to all interventions is warranted to allow the reader to place the findings within context.

8. The conclusion needs revision to be consistent with actual study findings.

MINOR ESSENTIAL REVISIONS

1. The abstract should be revised to accurately report the study in sufficient detail to stand alone. Was the allocation stratified for the two settings (nursing home and community)? Methods should describe the DBRCT design of the study not the background. The design would be more clearly described as FOE with SE or RT and each of these groups being either nutritionally supplemented or not. Describe the key components of the exercise (ie. 45min program incorporating warm up, functionally-oriented exercises and 20min of either resistance training or standard exercises) and nutrition interventions (ie. multinutrient to provide xx% of RDA for energy, etc). State all outcome measures. Results should report data alone, not interpretation. P=0.05 is not significant. Revise the conclusion as the data does not support this statement.

2. Define ‘all-inclusive nutritional supplementation’.

3. There are some sections that are either unnecessary or repetitive – Methods, paragraph commencing with ‘the actual study design envisaged …..’.

4. Comment on inter-rater reliability is warranted given data was collected by both nursing staff and physiotherapists. Was the outcome assessment blind? Was the outcome assessment performed by the Project Leader? If not then what did the Project Leader do? If it was just the data management then this section of the sentence is unnecessary.

5. It is not clear what criteria were used for overweight and underweight. This section implies that only overweight or underweight older adults were included however a BMI >19 suggests that the underweight would have been excluded. In addition the data presented in Table 1 suggests the participants were within the desirable BMI range for older adults.

6. The exercise descriptions could be described more succinctly. Remove anecdotes, justify selection of exercises in one sentence, suggest high intensity
be reserved for challenge as opposed to frequency. Clarify if breathing and relaxation exercises were within the 45 min period or in addition. It is not clear if the standard exercises took 10min + 3 30sec breaks, where the other 8.5min of the 20min standard exercise went. Likewise it is not clear how the 20min for the PRE was attained.

7. The prescription of the nutritional supplement requires clarification. It seems that the authors believe they would increase energy intake by 20% and vitamin and mineral intake by 25% through provision of 200ml per day. The authors should declare whether the aim was to meet or exceed the daily allowances. 100% adherence is rare in previous literature, please describe how this was measured and any quality control procedures used to ensure an accurate record was kept. In addition what strategies were used in both settings to encourage consumption, how was taste fatigue overcome when only a single supplement of one flavour was available? Suggest move the section on recommendations by the company to the limitations section of the manuscript. Indeed, it would be far better to determine how much of a shortfall remained after diet and supplement intake was determined rather than assume that participants would all have required between 1-3 servings of nutridrink. What difference was there between participants who consumed the supplements and those who did not? More information on the placebo supplement would be beneficial – was the only difference 41kcal (or 300-41kcal)? What about differences in other nutrients, namely protein? How was the supplement administered in the community setting?

8. The statistics appear relevant however the section on the 0-2 scale is unclear, please clarify perhaps by giving some examples. Furthermore it is not clear whether the analysis is a 4 group comparison as Table 3 suggests that only 2 groups were compared at any one time: the 2 nutritional supplement groups and the 2 exercise groups without nutritional supplements. The primary outcome analysis should be a 4 way comparison. If the P-values in the tables are referring to the Bonferroni comparisons the overall P-value should be included somewhere in the table for completeness.

9. The authors appear to be resistant to implementing individualised approaches to care despite this being usual and safest practice, particularly when dealing with exercise and diet modifications amongst older adults. Please clarify your position on this issue.

10. Much of Table 1 is surplus to requirements and could be removed as the authors do not make any mention of much of this content. Table 2 is unnecessary. Only between group comparisons are justified for inclusion as Tables. Within group are for interest only and could be simply described in the text. Figure 1 – clarify if the n-values assessed (ie. 19, 21, 19, 21) were the n-values analysed – non intention to treat.

DISCRETIONARY REVISIONS

1. Consider acknowledging the work of Breen et al – review published in 2007 in Geriatr Gerontol Int. Other references would also be beneficial – page 11 after high anxiety; page 12 after stating that functionally orientated exercises are
commonly acknowledged to universally well tolerated.

2. Consider altering the terminology used to describe the free-living elderly to recently hospitalised older adults.

3. Remove ‘present’ that appears in front of the term authors throughout.

4. Consider altering 301 original volunteers to 301 potential participants.

5. Consider rearranging the order of the methods section, commencing with study design (including stratification if accurate), recruitment (including inclusion and exclusion criteria), baseline data collection (including description of outcome measures), randomisation, outcome assessment (including who performed and timing), statistical analyses.

6. A table would be useful to provide examples of the exercises completed.

**Level of interest:** An article of importance in its field

**Quality of written English:** Needs some language corrections before being published

**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.