

Reviewer's report

Title: A factorial-design cluster randomised controlled trial investigating the cost-effectiveness of a nutrition supplement and an exercise programme on pneumonia incidence, walking capacity and body mass index in healthy older people living in Santiago, Chile: the CENEX study protocol [ISRCTN48153354]

Version: 1 Date: 19 April 2007

Reviewer: Marion McMurdo

Reviewer's report:

General

This paper is the description of the evolution of the design of a highly ambitious and novel pragmatic randomised trial.

It is clearly and well written and illustrates the practical challenges and frustrations of translating a paper protocol into the real world.

There have been many claims regarding nutritional interventions in later life and immune function – some now discredited – so this trial is of particular interest. If the intervention does reduced episodes of pneumonia, then the clinical community will be convinced that this is worthwhile. The benefits of exercise in later life are much better documented, and this study uses the 6 minute walking distance as the outcome measure to assess this. The 6 MWT is well validated in older people, although there is much controversy around its clinical meaning.

The use of a combined intervention (i.e. nutrition and exercise) is fascinating, and this trial will make a very important contribution to the world literature. I look forward to the results with keen anticipation.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1. More information on the exercise sessions is necessary. Are these to be done in groups or on a one-to-one basis? Are all the sessions to be supervised? How will adherence be recorded? Adherence should be captured to allow a correct interpretation of the change in 6MWT results.
2. Recall of falls has been shown to be very poor, and to capture meaningful data these should be recorded prospectively in daily diaries¹. It would be useful for the authors to clarify why they have opted for a recall method.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Discretionary Revisions (which the author can choose to ignore)

What next?: Accept after discretionary revisions

Level of interest: An article of importance in its field

Quality of written English: Acceptable

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