

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:** 24 June 2007

Reviewer: Obioha Ukoumunne

Reviewer's report:

General

Dangour and colleagues have given a clear and detailed account of the rationale and methods used for their trial of the effects of a nutrition supplement and exercise programme on pneumonia incidence and walking capacity. The methods they have used are appropriate for their aims and study design.

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

None.

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

1) On page 5, paragraph 4 the authors report that 8 additional clusters were randomised between the nutrition and control arms of the trial to compare the pneumonia outcome. I wondered if these clusters are also to be included for the walking capacity outcome, as appeared that none of these 8 clusters will receive the exercise intervention. As these clusters would be in the control arm for comparison of the walking capacity outcome I wondered if this might upset the balance of the randomisation in some way. It would be helpful if this was clarified in a revised version of the paper.

2) The sample size calculations seem to allow for clustering in the appropriate manner. I thought it might be useful for readers if the authors provided an appropriate reference for the method used (such as Hayes RJ Bennett S. Simple sample size calculation for cluster-randomized trials. *Int. J. Epidemiol.* 1999; 28: 319 - 326.) as sample size adjustments using the coefficient of variation of the outcome across clusters are less common and well understood than those based on the intra-cluster correlation of the outcome within clusters.

Discretionary Revisions (which the author can choose to ignore)

None.

What next?: Accept after minor essential revisions

Level of interest: An article of outstanding merit and interest in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.